

# ELFE - FRENCH LONGITUDINAL STUDY FROM CHILDHOOD

Last update : 05/07/2021

Head :

Charles Marie-Aline, "Elfe" INED-Inserm joint unit  
Geay Bertrand, ?Elfe? INED-INSERM joint unit

Responsible organization :

French National Institute for Demographic Studies (INED)  
French National Institute for Health and Medical Research (INSERM)

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

- Track changes in the child's living conditions (family, social environment, etc.) and measure their impact on his or her physical and mental development.
- Study the interactions between these living conditions and the child's school career
- Measure the impact of events during pregnancy and the child's health at birth on the latter's subsequent development
- Observe eating habits and their effects on growth (overweight, obesity)
- Assess the child's exposure to chemical, physical or environmental pollutants
- Measure the incidence and prevalence of childhood pathologies at different stages in growth
- Study associations between pathologies and exposure to environmental pollutants

Elfe is one of the two cohorts making up the RECO-NAI research platform, the other being Epipage

2. The general aim of this platform is to set up an infrastructure to support the collection, highly secure storage and distribution of data on pregnancy, birth and children. The platform will use the information yielded by the child cohorts, both followed from birth, to address key issues in the areas of children's health, development and socialization from an overarching, multidisciplinary perspective. It will also ensure that the cohorts are given a high profile in the world of academic research (French and international), as well as among bodies, organizations and manufacturers with an interest in children. This will ensure optimum use of the data collected and promote their dissemination.

## Inclusion criteria

- Children born after 33 weeks of pregnancy
- single or twin pregnancy
- in mainland France
- mother aged 18 years and over

# CONSTANCES - COHORT OF CONSULTANTS FROM HEALTH EXAMINATION CLINICS

Last update : 05/14/2014

Head :

Zins Marie, UMS 011 Cohortes épidémiologiques en population

Goldberg Marcel, UMS 011 Cohortes épidémiologiques en population

Responsible organization :

Université Versailles Saint Quentin en Yvelines (UVSQ)

Inserm

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

The objective is to establish a major epidemiological representative cohort of the general population and large workforce, in order to contribute to the development of epidemiological research and to provide information regarding public health.

- This is an infrastructure for epidemiological research based on the active workforce, quality and diversity of data and surveillance procedures. Objectives focus on the epidemiology of chronic illness, ageing, behaviour and the environment, as well as determining occupational and social health factors. It may also allow projects to be initiated for various topics, given to the wide accessibility for researchers.

- This is a public health tool that supports the State and CNAMTS public health objectives and assesses the achievement of these objectives through a comprehensive monitoring tool and the collection of diverse information, due to the varied and supplementary methods that call on various data sources.

- This is an epidemiological monitoring tool through a partnership established with the French Institute for Public Health Surveillance (InVS) (particularly on the topic of occupational risk from the Department of Occupational Health (DST)-InVS).

## Inclusion criteria

Adults between 18 and 69 years old and affiliated with the General Social Security Fund.

# E4N - EPIDEMIOLOGICAL STUDY CONCERNING THE CHILDREN OF E3N WOMEN

Last update : 12/21/2020

Head :

Severi Gianluca, Inserm - CESP, Team "Health across Generations"

Responsible organization :

Paris Saclay University

Inserm - Institut National de la Santé et de la Recherche Médicale

Gustave Roussy Institute

## Type of database

Study databases

## **Study databases (details)**

Cohort study

### **Main objective**

The familial E3N-E4N study purpose is to study health in relation to the modern way of life in people of the same family over three generations.

The E4N study aims to extend the E3N study by following the descendants of women who participated in the E3N study. The objective is to better understand the onset of major diseases, from genetics, family environment and the environment outside the family.

As well as gathering a large amount of prospective epidemiological data, E4N cohort permit the collection of important information concerning phenotypes and genetics.

### **Inclusion criteria**

Women included in the E3N cohort (G1),

Fathers of E3N women's children (G1)

Sons and daughters of E3N women (G2),

Grandchildren of E3N women (G3).

## **E3N STUDY - THE FRENCH E3N PROSPECTIVE COHORT STUDY**

Last update : 12/21/2020

Head :

Severi Gianluca, Inserm - Centre de Recherche en Épidémiologie et Santé des Populations (CESP) - Team Exposome and Heredity

Boutron-Ruault Marie-Christine, Inserm - Centre de Recherche en Épidémiologie et Santé des Populations (CESP) - Team Exposome and Heredity

Responsible organization :

Institut National de la Santé et de la Recherche Médicale - Inserm

Université Paris-Saclay

Institut Gustave Roussy

### **Type of database**

Study databases

## **Study databases (details)**

Cohort study

### **Main objective**

Detecting risk factors of cancer and chronic pathologies in women

### **Inclusion criteria**

Women born between 1925 and 1950 and affiliated with MGEN (Mutuelle Générale de l'Education

nationale)

## TEMPO - EPIDEMIOLOGICAL TRAJECTORIES IN THE POPULATION

Last update : 01/13/2021

Head :

Maria Melchior, UMRS 1136 - Equipe de recherche en épidémiologie sociale (ERES)

Responsible organization :

INSERM - Institut National de Santé et Recherche Médicale

### Type of database

Study databases

### Study databases (details)

Cohort study

### Main objective

General objective: study social health inequalities in mental health and addictive behaviors in young adults, accounting for individual and family characteristics.

Secondary objective: study health and health behaviours in young adults linked to their social, professional and family conditions.

In the context of the data collection in 2020, during the Covid-19 pandemic: analysis of the epidemic and lockdown consequences on mental health and addictive behaviours considering prior mental health and addictive behaviours and the evolution of economic and professional conditions during lockdown.

### Inclusion criteria

Young adults (22-35 years old in 2009), with one of the parents participating to the GAZEL cohort

## NUTRINET-SANTE - NUTRINET-HEALTH

Last update : 05/12/2015

Head :

Hercberg Serge, Unité de Recherche en Epidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Chantal Julia, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Touvier Mathilde, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Mejean Caroline, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Peneau Sandrine, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Fezeu Léopold, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Galan Pilar, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Kesse Emmanuelle, Unité de Recherche en EPidémiologie Nutritionnelle (UREN), U557 Inserm / U1125 Inra / Cnam / Université Paris 13 (Sorbonne Paris-Cité)

Castetbon , USEN

Responsible organization :

Institut National de la Santé et de la Recherche Médicale

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

General objective: to understand the relationship between nutrition and health and to investigate factors that determine dietary patterns.

1. To study the relationship between nutrient intake, food and dietary patterns as well as:
  - overall and specific mortality (cancer or cardiovascular disease);
  - The impact of cancer, cardiovascular disease, obesity and excess weight, type 2 diabetes, arterial hypertension, dyslipidemia, metabolic syndrome and quality of life.
2. To investigate factors that determine dietary patterns (sociological, economical, cultural, biological, etc.), nutritional status and health.
3. To monitor trends in the population's nutrient intake and nutritional status over time.
4. To evaluate the impact of public health campaigns or initiatives (awareness, perception, effectiveness, etc.).

## Inclusion criteria

Internet users (over 18 years old) who agreed to participate in the study for 5 years (at least) by answering questionnaires on diet (3 dietary records at baseline over 3 weeks) + questionnaires on physical activity + weight, height, + lifestyle + health questionnaire.

## **HOME-COV - HOSPITALIZATION OR OUTPATIENT MANAGEMENT OF PATIENTS WITH A PROVEN OR PROBABLE SARS-COV-2 INFECTION**

Last update : 02/05/2021

Head :  
DOUILLET Delphine

Responsible organization :  
CHU Angers

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

the composite rate of adverse outcomes [ Time Frame: day 7 ]

Adverse outcomes include intubation with mechanical ventilation requirement and death (Stage ? 6 on "Ordinal Scale for Clinical Improvement" of the World Health Organization) within 7 days after inclusion.

## Inclusion criteria

The rate of hospitalization [ Time Frame: 24 hours ]

The rate of patients hospitalized after admission to the emergency room including patients discharged home more than 24 hours after admission.

It will be analyzed in a hierarchical approach, only if first primary objective is positive i.e. non-inferiority of HOME-CoV strategy versus current practice on the rate of adverse outcomes.

# SEROCOVID - ETUDE ÉPIDÉMIOLOGIQUE DE PRÉVALENCE DU STATUT IMMUNOLOGIQUE COVID-19 PAR L'UTILISATION DE TESTS SÉROLOGIQUES RAPIDES D'ORIENTATION DIAGNOSTIQUE DANS LES ÉTABLISSEMENTS SANITAIRES ET MÉDICO-SOCIAUX DU GROUPE UNIVI

Last update : 10/01/2021

Head :  
HARBOUN Marc

Responsible organization :  
Groupe UNIVI

## Type of database

Bases de données issues d'enquêtes

## Study databases (details)

Etudes transversales non répétées (hors enquêtes cas-témoins)

## Main objective

Etudier la prévalence et le profil sérologique (présence d'anticorps et donc du contact avec le SARS COV2) chez des résidents et des personnels soignants d'EHPAD asymptomatiques (sans symptômes évoquant une infection en cours à COVID 19), ainsi que celui des personnels soignants asymptomatiques des établissements sanitaires du groupe UNIVI.

## Inclusion criteria

Groupe Résidents :

- Résidents des EHPAD participants
- Ayant bénéficié récemment d'un test sérologique rapide d'orientation diagnostique du COVID-19
- Ayant donné leur accord

Groupe Professionnels :

- Tous les personnels (médecins, infirmier(e)s, cadres de santé, aide-soignant(e)s, masseur-kinésithérapeutes, ASH, brancardiers, psychologues, diététicien(ne)s, personnels administratifs, secrétaires médicales, personnels intervenant en consultations et hôpitaux de jour..)
- Ayant bénéficié récemment d'un test sérologique rapide d'orientation diagnostique du COVID-19
- Ayant donné leur accord

## ACICOVID - CARDIAC ARREST INCIDENCE AND OUTCOME AMONG PATIENTS WITH COVID-19 IN FRENCH ICUS

Last update : 12/08/2020

Head :

CHELLY Jonathan

Responsible organization :

Centre Hospitalier Intercommunal Toulon La Seyne sur Mer - Délégation à la Recherche Clinique Promotion

## Type of database

Others

## Main objective

To report the incidence of Intensive Care Unit Cardiac Arrest (ICUCA) among patients hospitalized in French Intensive Care Unit (ICU) for COVID-19.

To report morbidity and mortality among COVID-19 patients admitted alive in ICU for an out-of-hospital cardiac arrest (OHCA) or an in-hospital cardiac arrest (IHCA).

## Inclusion criteria

- ? Patients admitted in intensive care unit with a documented SARS-CoV-2 disease
- ? For an out-of-hospital or an in-hospital cardiac arrest
- ? Or an in-hospital cardiac arrest
- ? Or presenting an unexpected in-intensive care unit cardiac arrest

## ONCOVID-19 - PROSPECTIVE ANALYSIS OF MORBI-MORTALITY OF PATIENTS WITH CANCERS IN ACTIVE PHASE OF TREATMENT SUSPECTED OR DIAGNOSED OF A SARS-COV-2 INFECTION

Last update : 12/11/2020

Head :

ASSAAD Souad

Responsible organization :

Centre Léon Bérard

## Type of database

Others

## Main objective

The primary objective is to describe the mortality of cancer patients under active anticancer treatment who underwent diagnostic procedures (positive or negative) for a suspicion of COVID-19.

The primary endpoint will be the mortality rate, defined as the proportion of patients who are dead 28 days after the date of the diagnostic procedure for the 2 cohorts of patients (positive and negative).

## Inclusion criteria

- Confirmed diagnosis of any type of solid or hematologic tumor;
- Ongoing anticancer treatment (cytotoxic, targeted therapy, immunotherapy or loco regional procedure, including radiotherapy, surgery or interventional radiology procedure) at the time of inclusion or within the last 3 months prior to inclusion (last treatment administration or last loco regional procedure) ;
- Patient with suspicion of COVID-19 (clinical symptoms of COVID-19 including fever ( $>38^{\circ}\text{C}$ ) and/or respiratory tract symptoms), either confirmed or not.

Note 1: Patients must have undergone diagnostic procedures: diagnostic test (positive or negative) and/or chest imaging.

Note 2: Patients will be eligible regardless of the presence of a neutropenia (either febrile or not)

- Patient and/or family did not decline data collection after complete information (information sheet)

# IMMUNONCOVID-20 - A PROSPECTIVE, CONTROLLED, RANDOMIZED, MULTICENTER STUDY OF THE EFFICACY OF AN AUTOPHAGY INHIBITOR (GNS561), AN ANTI-NKG2A (MONALIZUMAB) AND AN ANTI-C5AR (AVDORALIMAB) COMPARED TO THE STANDARD OF CARE IN PATIENTS WITH ADVANCED OR METASTATIC CANCER AND SARS-COV-2 (COVID-19) INFECTION.

Last update : 12/15/2020

Head :

AVRILLON Virginie

Responsible organization :

Centre Léon Bérard

## Type of database

Others

## Main objective

The main objective is to compare versus standard of care short-term mortality rates in advanced or metastatic cancer patients who are positive for COVID-19 treated with an autophagy inhibitor (GNS561), an anti-NKG2A (monalizumab) or an anti-C5aR (avdoralimab).

The primary endpoint will be the 28-day survival rate, defined by the proportion of patients still alive 28 days after randomization.

The 28-day survival rate will be described in each arm of each cohort.

## Inclusion criteria

Inclusion criteria

I1. Age 18 or older at the time of enrolment for women and age 60 or older at the time of enrolment for men.

I2. Histologically or cytologically confirmed diagnosis of advanced or metastatic hematological or solid tumor (hematological or solid tumor, any type and any localization).

I3. Documented diagnosis of COVID-19 (diagnostic test performed in a certified laboratory) without indication of transfer in a resuscitation unit. .

Nota Bene : A maximum time of 7 days may have elapsed between the date of first symptoms and the date of consent for patient cohort 1 (mild). In cohort 2 (severe), up to 10 days may have elapsed since the first symptoms.

I4. Cohort 2: patients with pneumonia confirmed by chest imaging, and an oxygen saturation (Sao<sub>2</sub>) of 94% or less while they are breathing ambient air or a ratio of the partial pressure of oxygen (Pao<sub>2</sub>) to the fraction of inspired oxygen (Fio<sub>2</sub>) (Pao<sub>2</sub>:Fio<sub>2</sub>) at or below 300 mg Hg.

I5. Multidisciplinary approach that patient is not eligible for a transfer to Resuscitation Unit (either due to underlying medical condition ? including cancer ? or due to lack of available bed).

Note: Item cancelled (addendum 2 ? October 2020)

I6. Life-expectancy longer than 3 months.

I7. Adequate bone marrow and end-organ function defined by the following laboratory results:

? Bone marrow:

- Hemoglobin ? 9.0 g/dL,

- Absolute Neutrophils Count (ANC) ? 1.0 Gi/L,

- Platelets ? 100 Gi/L;

? Hepatic function:

- Total serum bilirubin ? 1.5 x ULN (except patients with Gilbert's syndrome who must have total serum bilirubin ? 3.0 x ULN),

- AST and ALT ? 5 ULN

? Renal function:

- Serum creatinine ? 2.0 x ULN or Cr. Cl. ? 30ml/min/1.73m<sup>2</sup> (MDRD or CKD-EPI formula);

I8. Willingness and ability to comply with the study requirements;

I9. Signed and dated informed consent indicating that the patient has been informed of all the aspects of the trial prior to enrollment (in case of emergency situation, please refer to protocol section 12.1 PATIENT INFORMATION AND INFORMED CONSENT);

I10. Women of childbearing potential (Appendix 1) are required to have a negative serum pregnancy test within 72 hours prior to study treatment start. A positive urine test must be confirmed by a serum pregnancy test;

I11. Women of childbearing potential and male patients must agree to use adequate highly effective contraception (Appendix 1) for the duration of study participation and up to 6 months following completion of therapy;

I12. Patient must be covered by a medical insurance.

Non-inclusion criteria

- E1. For cohort 1 only : Patient currently receiving therapy with an anti-NKG2A.
- E2. For cohort 2 only: Patient currently receiving therapy with an anti-C5aR.
- E3. Contraindication to treatment with monalizumab (cohort 1 only) or avdoralimab (cohort 2 only) as per respective IB, including known hypersensitivity to one of these study drugs or severe hypersensitivity reaction to any monoclonal antibody.
- E4. For cohort 1 only : Patient known to have intolerance or hypersensitivity to chloroquine or any quinoline derivates (quinine, chloroquine, tafenoquine, hydroxychloroquine, mefloquine). Patients previously exposed to CQ, HCQ or other quinoline derivates should have interrupted their treatment at least 72h prior to randomization.
- E5. Patient has active autoimmune disease that has required systemic treatment in the past 3 months before the date of randomisation or a documented history of clinically severe autoimmune disease, or a syndrome that requires systemic steroids at doses higher than 10 mg/d prednisone equivalents or immunosuppressive agents.
- a. Note 1: Patients with vitiligo or resolved childhood asthma/atopy would be an exception to this rule. Patients that require intermittent use of bronchodilators or local steroid injections would not be excluded from the study. Patients with hypothyroidism stable on hormone replacement or Sjögren's syndrome will not be excluded from the study.
- b. Note 2: Patients may receive corticosteroids as required for the management of SARS-CoV-2-related symptoms.
- E6. Patient requires the use of one of the following forbidden treatment during the study treatment period, including but not limited to :
- ? Major surgery.
- ? Live vaccines. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, chicken pox, yellow fever and BCG. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however intranasal influenza vaccines (e.g. Flu-Mist®) are live attenuated vaccines, and are not allowed.
- E7. Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or greater), myocardial infarction within 3 months prior to the date of randomisation unstable arrhythmias or unstable angina, Known Left Ventricular Ejection Fraction (LVEF) < 50%.
- a. Note: Patients with known coronary artery disease, congestive heart failure not meeting the above criteria must be on a stable medical regimen that is optimized in the opinion of the treating physician and in consultation with a cardiologist if appropriate.
- E8. Patient has known active hepatitis B (chronic or acute; defined as having a positive hepatitis B surface antigen [HBsAg] test at screening), known active hepatitis C (Patients positive for hepatitis C virus (HCV) antibody are eligible only if PCR is negative for HCV RNA at screening) or known Human Immunodeficiency Virus (HIV) infection (HIV 1/2 antibodies).
- E9. Prior allogeneic bone marrow transplantation or solid organ transplant in the past.
- E10. Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the trial, interfere with the subject's participation for the full duration of the trial, or is not in the best interest of the subject to participate, in the opinion of the treating Investigator.
- E11. Has known psychiatric or substance abuse disorders that would interfere with cooperation with the requirements of the trial.
- E12. Pregnant or breastfeeding patient, or expecting to conceive children within the projected duration of the trial, starting with the screening visit through 6 months after the last dose of study drugs.

## RDCOVID19 - INCIDENCE AND CHARACTERISTICS OF RETINAL DETACHMENT DURING CORONAVIRUS-19 PANDEMIC

Last update : 12/15/2020

Head :

Paques Michel, Ophthalmology

Responsible organization :  
Quinze-Vingt Hospital

## Type of database

Health relevant administrative databases

## Main objective

To assess the impact of the Covid-19 pandemic and subsequent lockdown on the number and clinical characteristics of patients with retinal detachment (RD) in a French public university eye hospital.

## Inclusion criteria

Single-center, retrospective non-interventional study. Patients consulting at the emergency room (ER) of Quinze-Vingts Hospital (France) for rhegmatogenous RD before and after instauration of the lockdown. Number of cases, delay between diagnosis and surgery, visual acuity were measured.

# ONCOVID-21 - EVALUATION OF A DDPCR TECHNOLOGY FOR THE SARS-COV-2 DETECTION BASED ON DIFFERENT TYPES OF SAMPLES IN CANCER PATIENTS WITH SUSPICION OF COVID-19 (SYMPTOMATIC)

Last update : 12/18/2020

Head :  
MASTROIANNI BENEDICTE, Medical Oncology Department

Responsible organization :  
CENTRE LEON BERARD

## Type of database

Study databases

## Study databases (details)

## Main objective

To determine the ddPCR ability to detect the SARS-CoV-2 in nasopharyngeal samples of symptomatic patients with suspected COVID-19 infection using an IgG serological assay (EUROIMMUN Anti-SARS-CoV2 ELISA IgG) as gold/reference standard (FDA validated commercial serologic test).

The primary endpoint will be the sensibility of the ddPCR assay for SARS-CoV-2 detection based on nasopharyngeal samples.

## Inclusion criteria

1. Age ≥ 18 years on the day of signing informed consent.
2. Confirmed diagnosis of any type of solid or hematologic tumor.
3. Ongoing anticancer treatment at the time of inclusion or within the last 3 months prior to inclusion (last treatment administration or last loco regional procedure)
4. Suspicion of COVID-19 infection. Patients must not have undergone diagnostic test and/or chest

imaging before inclusion.

\* At least one of the following clinical symptoms: fever ( $>38^{\circ}\text{C}$ ), dry cough, fatigue, pulmonary involvement (febrile respiratory infection or respiratory difficulties), pharyngalgia, headaches, myalgia, gastrointestinal symptoms including abdominal pain and diarrhea, anosmia and agueusia, radiological signs of pneumonia as described by Shi et al.

5. Covered by a medical/health insurance.

6. Signed and dated informed consent form.

## RÉ-CONF-ISS - RÉUNION ISLAND, LOCKDOWN, SOCIAL INEQUALITIES IN HEALTH

Last update : 11/02/2022

Head :

FIANU Adrian, CIC1410 / EQUITY (CERPOP)

Responsible organization :

CHU de la Réunion

### Type of database

Study databases

### Study databases (details)

Not-repeated cross-sectional studies (except case control studies)

### Main objective

Primary objective:

To describe, just after the lockdown implemented for tackling SARS-Cov-2 epidemic, the self-reported state of health of the Reunionese population according to the residential district deprivation level.

Secondary objectives:

- To describe, just after the lockdown event, the self-reported state of health of the Reunionese population according to the housing conditions experienced during the lockdown.

- To describe, just after the lockdown event, the self-reported state of health of the Reunionese population according to the individual socioeconomic characteristics: age class and gender, employment status and socioprofessional category, education level.

- To compare the self-reported general stress level between the regional studies conducted on Réunion island: during the lockdown event (Confin-Aou study) versus after the lockdown event (Ré-Conf-ISS study).

- To compare the psychologic impact of the lockdown event between France main land and Réunion island using the results from the Epidemic national survey and the Ré-Conf-ISS regional survey respectively.

### Inclusion criteria

- Major (aged 18 years and older)

- Living on the island before 17 March 2020

- Stayed on the Réunion territory within all through the lockdown event (between March 17th and May 11th)
- Without curatorship

## **SOPRAC - PRIMARY CARE FOR COVID-19 IN THE AUVERGNE-RHÔNE-ALPES FRENCH REGION**

Last update : 01/03/2021

Head :

Letrilliart Laurent, HESPER

Responsible organization :

Hospices Civils de Lyon & Université de Lyon 1

### **Type of database**

Study databases

### **Study databases (details)**

Not-repeated cross-sectional studies (except case control studies)

### **Main objective**

To estimate and describe, during the epidemics, the temporal evolution of the following indicators in the patient list of the primary care facilities in the Auvergne-Rhône-Alpes French region: incidence of the clinically suspect COVID-19 cases, incidence of the biologically confirmed COVID-19 cases, clinical characteristics of these cases.

### **Inclusion criteria**

- Patient M/F
- Suspect or confirmed COVID-19 case attending a general practice or a multiprofessional health home in the Auvergne-Rhône-Alpes French region

## **BBCOVID - NASAL AND SALIVARY DETECTION OF THE SARS-COV-2 VIRUS AFTER ANTIVIRAL MOUTH RINSES**

Last update : 01/08/2021

Head :

CARROUEL Florence, Laboratory "Systemic Health Course", EA4129

Responsible organization :

Laboratory "Systemic Health Course", EA4129

### **Type of database**

Others

### **Main objective**

Change from Baseline amount of SARS-CoV-2 in salivary samples at 7 days

Quantitative PCR experiments will be performed and a quantitative analysis of the salivary samples will be made

## Inclusion criteria

- ? Age: 18-70 years
- ? Clinical diagnosis of Covid-19 infection by the patient's general practitioner and hospital doctor
- ? Clinical signs started less than 48 hours ago.
- ? Virological confirmation: not necessary but possible.
- ? Understanding and acceptance of the trial.
- ? Written agreement to participate in the trial

# DISTANCING - SOCIAL DISTANCING AND PRO-SOCIALITY IN TIMES OF ACUTE SANITARY CRISIS

Last update : 01/13/2021

Head :

Villeval Marie Claire , GATE UMR5824

Responsible organization :

CNRS

## Type of database

Autres

## Main objective

L'étude repose sur une démarche d'économie comportementale et expérimentale permettant d'éliciter les préférences sociales des individus à travers la prise de décisions incitées monétairement.

L'expérience est menée en ligne avec 350 participants qui se sont connectés chaque semaine du 18 mars au 24 juin sur notre site (15 sessions). Chaque session est similaire et comprend un test d'orientation en termes de valeurs sociales (SVO ; Murphy et al., 2011), un jeu de confiance et un questionnaire pour mesurer le degré de distanciation sociale avec la famille et les amis, et la norme sociale face à la violation de la règle de distanciation. Ces mesures permettent d'identifier le degré de pro-socialité de l'individu, sa propension à faire confiance à autrui et à reciprocquer cette confiance, sa perception de la norme sociale en matière de violation de la règle de distanciation sociale. La répétition des mesures chaque semaine pendant 3 mois permet de mesurer l'évolution des préférences en fonction du durcissement des mesures de confinement puis de leur levée.

## Inclusion criteria

Appartenance à la base de sujets expérimentaux volontaires de Gate-Lab.

# PSY-GIPO2C - PSYCHIATRY PROFESSIONALS AND COVID 19 IN EUROPE: PSYCHOLOGICAL IMPACT MANAGEMENT AND CRISIS AND POST-CRISIS ORGANISATION

Last update : 01/13/2021

Head :

Frédéric DENIS

Responsible organization :  
EA 75-05

## Type of database

Others

## Main objective

The project will provide an intelligent, European-wide perspective, to enable the sharing of innovative practices in a very operational manner.

## Inclusion criteria

Approximately 2,000 psychiatric care professionals,

# NUTRICOVID30 - FOOD INTAKE AND WEIGHT LOSS IN THE COURSE OF COVID-19 INFECTION. A LONGITUDINAL STUDY OF THE MULTICENTER NUTRICOVID30 COHORT

Last update : 01/13/2021

Head :

Marie-France Vaillant, Nutrition

Responsible organization :

Grenoble Alpes University Hospital

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

The aim of this study was to describe the nutritional impact of COVID-19 infection on adult inpatients on the short- to mid-term (up to 30 days after hospital discharge), using food intake and weight measurements. It also aimed to identify factors associated with a decrease in food intake and weight.

## Inclusion criteria

- Adults inpatients with a confirmed diagnosis of Covid-19
- 30 days delay after discharge from hospital
- information and no opposition for data collection and call interview

# VIGIL - USE OF PCR-SARS-COV-2 IN CHILDREN (VIGIL)

Last update : 05/05/2021

Head :

JUNG Camille

Responsible organization :  
Créteil Intermunicipal Hospital

### Type of database

Study databases

### Study databases (details)

Cohort study

### Main objective

Percentage of patients positive for Covid-19

### Inclusion criteria

Children <15 years

indication for PCR or rapid antigen test for Covid-19

## COVIGENET - COHORT OF PATIENTS WITH COVID-19: CREATION OF A BIOLOGICAL SAMPLE COLLECTION WITH CLINICAL CHARACTERISATION

Last update : 05/05/2021

Head :

MAITRE Bernard

Responsible organization :

Créteil Intermunicipal Hospital

### Type of database

Others

### Main objective

Investigation for a phenotype/genotype correlation modulating the severity of Covid-19 disease

### Inclusion criteria

Proven diagnosis of COVID-19 (based on RT-PCR or chest CT-scan)

Patients of all ages

Registered with the general social security scheme

Consent form signed by the patient or by the legal representatives for minors

## COVISAL - COMPARISON OF RESULTS, FEASIBILITY AND ACCEPTABILITY OF MOLECULAR DETECTION OF COV2-SARS BETWEEN NASOPHARYNGEAL SWAB SAMPLES COLLECTED IN VIROLOGICAL TRANSPORT MEDIA AND SALIVARY SPIT SAMPLES

Last update : 01/13/2021

Head :

DEMAR Magalie, university laboratory

Responsible organization :

Centre Hospitalier de Cayenne

## Type of database

Others

## Main objective

Comparison of the results obtained by the molecular detection of SARS-CoV2 in the 2 types of samples: nasopharyngeal swab taken from the virological transport medium and salivary spit.

## Inclusion criteria

Patient presenting to Cayenne Hospital with an indication to perform a COVID diagnostic test (symptomatology, contact case)

Men and women from 3 years to over 75 years old

# LEARNINCOV - LEARNING IN PANDEMIC TIMES: ANXIETY, COGNITIVE CAPACITIES AND DECISION-MAKING OF UNIVERSITY STUDENTS

Last update : 01/21/2021

Head :

Timothée Demont, Aix-Marseille School of Economics

Eva Raiber, Aix-Marseille School of Economics

Responsible organization :

AMSE

## Type of database

Study databases

## Study databases (details)

Case control study

## Main objective

This research project aims at better understanding the consequences of this major, sudden, and society-wide shock on university students who, by definition, are at the doorstep of their professional life and need substantial cognitive resources to make the most of their university training. We investigate the following question: Does the anxiety generated by the Covid-19 pandemic affect the learning and decision-making capacities of students and, if yes, by how much and through which channels? We specifically test the impact of the negative labor-market and social consequences of the Covid-19 crisis on students' cognitive abilities, confidence and locus of control, expectations, risk preferences, and mental health.

In order to uncover mechanisms and allow sharper recommendations about student support policies, our

study is designed to quantify the relative importance of worries regarding future labor-market opportunities and the impairment of social life and network, test the role of the competitive pressure, and perform a variety of heterogeneity analyses to identify particularly vulnerable groups such as female, low economic background and depression-prone students.

## **Inclusion criteria**

The survey will include around 2,000 randomly-selected students from different faculties and at different stages of their studies at the Aix-Marseille University (AMU). The student body at the AMU is diverse with regard to gender composition and socio-economic background of the students. Accessing participants of different characteristics and from different fields and levels of study will allow us to uncover the underlying mechanisms.

# **COVID-IMPACT - PREVALENCE AND DEVELOPMENT OF POST-TRAUMATIC STRESS DISORDER AND ANXIETY AND DEPRESSIVE SYMPTOMS AMONG AP-HP STAFF DURING THE COVID-19 EPIDEMIC**

Last update : 01/29/2021

Head :

PELISSOLO Antoine , Psychiatry

Responsible organization :

Assistance Publique - Hôpitaux de Paris

## **Type of database**

Study databases

## **Study databases (details)**

Repeated cross-sectional studies (except case control studies)

## **Main objective**

The epidemic of coronavirus induces a major influx of patients implying a rapid modification of the organizations, a work overload and a significant stress for the care teams and supports of the hospitals of the Assistance Publique - Hôpitaux de Paris (AP-HP) . To this is added the impact on each professional of the large number of very severe patients to be treated, of death and the anxiety of contamination, reinforced by the actual cases of staff themselves sick. Emergency phone numbers for professionals in the event of psychological suffering were quickly put in place at the AP-HP and Hospitals level. The objective of this study is to assess the psychopathological and psycho-traumatic consequences of this exceptional situation on the staff, during the epidemic and at a distance from it, in order to be able to target the solutions to be implemented. Hypothesis is that some personnel may develop one or more of the following disorders: adjustment disorder or other anxiety disorder, acute stress disorder, post-traumatic stress disorder (PTSD), and depressive episodes as defined in the DSM-5. This study also aims to assess effect of support measures put in place, by comparing the evolution of those who benefited from those who did not use them, as well as the risk factors specific. The results will make it possible to have an estimate of the percentage of people who may require specific support, and to identify the staff most at risk, and thus predict the importance of the circuits and structures for support of staff which will be necessary in the short and long term. The main anticipated risk factors are: being a nurse, having a low number of years of professional experience, and being on the front line of care for affected patients.

## **Inclusion criteria**

Inclusion Criteria:

AP-HP professionals on duty during the COVID epidemic agreeing to participate in the three stages of the study.

Exclusion Criteria:

none

# **COVIDOR - ÉTUDE ÉPIDÉMIOLOGIQUE DU TEST COVID-19 PRESTO CHEZ LES AGENTS DES COLLECTIVITÉS TERRITORIALES DU LOIRET ET ORLÉANS MÉTROPOLE. CORRÉLATION DU TAUX D'IGM EN FONCTION DU CONTACT AVEC LE PUBLIC**

Last update : 03/12/2021

Head :

Serreau Raphael, URC PARADICT-O

Responsible organization :

Unité de Recherche PARADICT-O - Service de Médecine - Orléans Métropole

## **Type of database**

Bases de données administratives pertinentes pour la santé

## **Main objective**

Estimer la séroprévalence de l'infection covid-19, à coronavirus (Sars-cov-2) chez des agents territoriaux des structures d'Orléans Métropole, dans la communauté de commune Terre Val de Loire, au centre de Gestion (CDG45) et dans La Région Centre Val de Loire mesuré par la présence d'anticorps anti Covid-19

Objectifs secondaires :

Déterminer un taux d'attaque du covid-19 chez les agents territoriaux en fonction des métiers en relation avec le public (ATSEM, Auxiliaires de Puéricultures, Gestion des déchets, Surveillance du Territoire,...) ou non

- Etablir la corrélation entre un contact Covid avéré et le poste occupé (contact avec le public ou non)
- Dépister des agents (en contact avec le public ou non) qui pourraient être contaminants et asymptomatiques.

## **Inclusion criteria**

Critères d'inclusion :

- Âge >18 ans
- Etre un agent des collectivités territoriales suivantes : Région Centre Val de Loire, CDG 45, CCTVL et Orléans Métropole, les élus sont considérés comme des agents territoriaux dans l'étude covidor et peuvent être inclus
- Etre volontaire pour se faire tester

Critères de non inclusion :

- Opposition (refus de participation) à l'étude
- Agents présentant des symptômes Covid 19 le jour de la visite

## **CHRONO-CONF - EFFET DU CONFINEMENT SUR LES RYTHMES CIRCADIENS DES PATIENTS INTEGRES DANS UN PARCOURS DE SOINS POUR UNE CHIRURGIE BARIATRIQUE**

Last update : 04/02/2021

Head :

BOREL Anne-Laure

Responsible organization :

CHU GRENOBLE ALPES

### **Type of database**

Bases de données issues d'enquêtes

### **Study databases (details)**

Etudes de cohortes

### **Main objective**

Evaluer l'influence du confinement à domicile sur l'évolution des horaires de sommeil et de prises alimentaires chez des sujets présentant un antécédent d'obésité.

Objectifs secondaires :

1. Evolution du poids durant le confinement
2. Evolution de la qualité de vie durant le confinement
3. Evolution de la quantité d'activité physique durant le confinement
4. Evolution du bien-être psychologique durant le confinement
5. Evolution professionnelle durant le confinement
6. Evolution de la sécurité alimentaire durant le confinement
7. Evolution de l'association entre changement de rythme circadien et changement (1) du poids, (2) de l'activité physique, (3), du bien-être psychologique

### **Inclusion criteria**

Critères d'inclusion :

Sujets adultes inclus dans les parcours de soins qui préparent puis suivent une chirurgie bariatrique au CHU Grenoble Alpes et au CH métropole-Savoie.

Sujets qui disposent d'une adresse e-mail et d'un accès internet.

Critères de non-inclusion :

Sujets refusant de participer

Sujets ayant séjourné dans un pays qui n'a pas organisé de confinement durant la pandémie COVID-19.

Critères d'exclusion secondaire :

Certains ne seront pas incluables si leurs coordonnées téléphoniques ont changé, ne disposant pas d'une adresse e-mail ou d'un accès internet.

La recherche inclut-elle des personnes ne présentant aucune affection ? non

Modalités de recrutement des personnes interrogées :

L'étude sera proposée par mail à tous les patients suivis au CHU Grenoble Alpes depuis 2013 et au CH métropole-Savoie depuis 2016 dans le cadre d'un parcours de soin de chirurgie bariatrique.

Modalités d'information et de traçabilité de la non- opposition :

Ce mail s'accompagnera d'une information sur l'étude permettant aux sujets de s'opposer à l'utilisation de leurs données dans cette étude.

## **CURIOSA - ETUDE DE LA RÉPONSE SÉROLOGIQUE CONTRE LE VIRUS SARS-COV-2 DANS 2 TYPES DE PERSONNEL, HOSPITALIER ET NON HOSPITALIER, À L'INSTITUT CURIE ET À L'INSTITUT PASTEUR**

Last update : 02/12/2021

Head :

Olivier Lantz

Thierry Rose

Responsible organization :

Institut curie

### **Type of database**

Study databases

### **Study databases (details)**

Cohort study

### **Main objective**

L'objectif de cette étude est de constituer une sérothèque prospective permettant l'étude de la prévalence et de la qualité de la réponse immune sérologique dirigée contre le virus SARS-CoV-2 au cours de la pandémie dans une population active en dehors de tout épisode infectieux aigu par le SARS-CoV-2, le personnel de l'Institut Curie (Siège, Hôpital et Centre de Recherche) et le personnel de l'Institut Pasteur ayant potentiellement divers niveaux d'exposition.

### **Inclusion criteria**

1) Personne, volontaire en dehors de tout épisode infectieux aigu par le SARS-CoV-2 \* (cf. paragraphe indication), et en capacité d'exercer son activité professionnelle sur un des 3 sites de l'Institut Curie, Paris, Orsay ou Saint Cloud, ou sur le campus de l'Institut Pasteur.

2) Personne âgée de 18 ans ou plus.

3) Information et consentement de la personne aux procédures liées à l'étude (cf. note d'information / consentement).

4) A partir de novembre 2020, personne ayant présenté au moins un des critères suivants depuis janvier 2020 :

? Un test de diagnostic du SARS-CoV-2 positif par PCR sur prélèvement naso-pharyngé ou test antigénique,

? Une sérologie SARS-CoV-2 positive,

? Une anosmie ou/et une agueusie,

? Une infection respiratoire\*\* associée à des signes digestifs\*\*

Pour le personnel exerçant à l'Institut Pasteur, quelles que soient les modalités de travail pendant le confinement. :

Personne ayant présenté au moins un des critères suivants depuis janvier 2020 :

- ? Un test de diagnostic du SARS-COV-2 positif par PCR sur prélèvement naso-pharyngé,
- ? Une sérologie SARS-CoV-2 positive,
- ? Une anosmie ou/et une agueusie,
- ? Une infection respiratoire\*\* associée à des signes digestifs\*\*

\*Sont considérés comme volontaires ne présentant pas d'infection active par le SARS-CoV-2 au moment de l'inclusion : personnes n'ayant pas de signes cliniques\*\* évocateurs d'une infection à SARS-CoV-2 au moment du prélèvement sanguin ou les ayant eu avec une fin des symptômes depuis plus de 7 jours.

\*\* fièvre, fatigue, toux, gêne respiratoire, essoufflement, perte de goût ou odorat, maux de tête, courbatures, conjonctivite ou rhume, troubles digestifs ( vomissement, diarrhée), que les signes aient entraîné ou non un arrêt de travail, un traitement et/ou une hospitalisation.

## **MININO-COVID - EXPLORATORY MULTICENTER OBSERVATIONAL STUDY TO ASSESS THE OUTCOME OF INFANTS WITH PERINATAL SARS-COV-2 INFECTION AND ITS LINK WITH THE NO PATHWAY: THE MINIPUBERTY HYPOTHESIS**

Last update : 02/12/2021

Head :

STORME Laurent, Neonatal Intensive Care Unit of the CHU of Lille; FHU 1000 days for health

PREVOT Vincent, Laboratory of Development and Plasticity of the Neuroendocrine Brain; Lille Neuroscience & Cognition; FHU 1000 days for health

Responsible organization :

CHU Lille

### **Type of database**

Study databases

### **Study databases (details)**

Case control study

### **Main objective**

To compare the follicle stimulating hormone (FSH) plasma concentrations measured at the postnatal age of 3 months between the three matched (on gestational age at birth, postnatal age and respiratory failure) newborn infants groups

### **Inclusion criteria**

- o Newborn infants (24 to 41 weeks gestational age) or young infants (< 3 months) admitted at the maternity ward or at the Department of Neonatology at Jeanne de Flandre Hospital, CHU of Lille with perinatal COVID-19 infection defined by:
- o Antenatal COVID-19 infection: pregnant women with positive PCR test at any time of the pregnancy;
- o Post-natal COVID-19 infection: newborn or young infants (< 3 months) with positive PCR test in pharynx or stools as part of their treatment.
- o Newborn infants (24 to 41 weeks gestational age) or young infants (< 3 months) admitted at the

maternity ward or at the Department of Neonatology at Jeanne de Flandre Hospital, CHU of Lille for severe cardiorespiratory diseases requiring inhaled NO treatment.

- o The control group without perinatal COVID-19 infection will be matched to the treatment group on gestational age at birth ( $\pm$  2 weeks of gestation), on postnatal age ( $\pm$  3 weeks) and respiratory failure.
- o No inclusion in another ante- or post-natal trial;
- o Written consents from both parents;

## **AUTOCOV - COMPARAISON DE STRATÉGIES BASÉES SUR LA RT-PCR OU LE TEST ANTIGÉNIQUE POUR LE DÉPISTAGE DE L'INFECTION À SARS-COV-2 EN POPULATION GÉNÉRALE À PARTIR D'AUTO-PRÉLÈVEMENTS.**

Last update : 05/07/2021

Head :

POZZETTO Bruno  
GAGNAIRE Julie

Responsible organization :

CHU SAINT-ETIENNE

### **Type of database**

Bases de données issues d'enquêtes

### **Study databases (details)**

Etudes transversales répétées (hors enquêtes cas-témoins)

### **Main objective**

L'objectif principal est d'évaluer, pour le dépistage de l'infection à SARSCoV-2, les performances d'une stratégie qui combinerait 1) un autoprélèvement salivaire associé à un auto-prélèvement nasal antérieur et 2) un test diagnostique antigénique directement réalisable sur le terrain, en comparaison avec la technique de référence de RT-PCR sur prélèvement salivaire récemment validée par la HAS.

Objectifs secondaires :

- Déterminer la prévalence de l'infection à SARS-CoV-2 dans la population testée par le test de référence;
- Déterminer la prévalence de la circulation des différents variants d'intérêt de SARS-CoV-2 dans la population testée;
- Evaluer l'acceptabilité des auto-prélèvements en fonction de l'âge et des catégories socio-professionnelles;
- Evaluer la praticabilité des deux stratégies de dépistage;
- Evaluer le rapport coût-efficacité de la nouvelle stratégie diagnostique par rapport à la technique de référence (RT-PCR sur salive);
- Renforcer l'adhésion aux gestes barrières et aux consignes d'isolement précoce des cas positifs par la réalisation de tests rapides et par un accompagnement par des personnes sensibilisées à l'approche motivationnelle;
- Evaluer l'accompagnement sanitaire des personnes à l'isolement;
- Evaluer sur un échantillon de sujets dépistés positifs ou négatifs, les connaissances relatives aux gestes barrières et aux consignes d'isolement par l'utilisation des tests rapides et par l'accompagnement des médiateurs de lutte anti-COVID.

## **Inclusion criteria**

- Sujet adulte ou sujet de 10 ans ou plus susceptible de fournir un autoprélèvement de salive et de nez antérieur
- Sujet ou tuteur légal ne s'opposant pas à l'auto-prélèvement et au recueil des données anonymisées dans le cadre de cette recherche
- Patients affilié ou ayant droit d'un régime de sécurité sociale

# **ANRS 0001 S COV-POPART - COHORTE VACCINALE COVID-19 DES POPULATIONS PARTICULIÈRES**

Last update : 08/23/2022

Head :

LAUNAY Odile

WTTKOP Linda

LOUBET Paul

Responsible organization :

INSERM-ANRS

## **Type of database**

Bases de données issues d'enquêtes

## **Study databases (details)**

Etudes de cohortes

## **Main objective**

Objectifs principaux communs à toutes les sous-populations :

Évaluer de manière standardisée dans chaque sous-population la réponse immunitaire humorale à la vaccination Covid-19 à 1, 6, 12, 24 mois après la première injection (schéma à une injection) ou après la deuxième injection du vaccin (schémas à deux ou trois injections) et évaluer de manière standardisée la réponse humorale 1 mois après la réception de la troisième injection chez les participants recevant une troisième injection selon les recommandations en vigueur.

Objectifs secondaires communs à toutes les sous populations :

1. Évaluer et caractériser la réponse immunitaire cellulaire lymphocytaire T (à INC, M06, M12 et M24) spécifique de l'antigène induite après la première injection (schéma à une injection) ou après la deuxième injection du vaccin (schémas à deux ou trois injections) dans chaque sous-population.
2. Comparer la réponse immunitaire humorale à 1, 6, 12, 24 mois après la première injection (schéma à une injection) ou après la deuxième injection du vaccin (schémas à deux ou trois injections) de chaque sous-population avec un groupe de sujets indemnes des conditions chroniques étudiées ou autres pathologies/traitements influençant la réponse immunitaire.
3. Comparer la réponse humorale après trois injections (M02) à celle après deux injections (M01) chez les participants ayant reçu une troisième injection selon les recommandations en vigueur.
4. Evaluer et caractériser la réponse immunitaire humorale pour les participants ayant reçu une dose de rappel avec un vaccin à ARNm selon les recommandations en vigueur.
5. Dans chaque sous-population, étudier les facteurs associés à la réponse immunitaire humorale à 1

mois et à la persistance de la réponse immunitaire humorale à 6, 12, 24 mois en fonction de l'âge, du stade de la maladie, des traitements, du type de vaccin (ainsi que des caractéristiques spécifiques aux sous-populations étudiées).

6. Comparer la réponse immunitaire humorale entre différentes sous-populations particulières.
7. Décrire la séroconversion pour les anticorps anti-nucléoprotéines à l'inclusion et pendant le suivi.
8. Caractériser immuno-virologiquement les échecs vaccinaux (infection à SARS-CoV-2 dans les délais définis par le protocole en vigueur).
9. Rechercher les déterminants génétiques de la réponse immunitaire selon la pathologie sous-jacente et les traitements en cours le cas échéant (réponse et résistance à la vaccination).

Objectifs secondaires de la sous-population de sujets non atteints d'une des conditions chroniques d'intérêt ou autres pathologies / sous traitement ayant une influence connue sur la réponse immunitaire et vaccinés avec une 1ère injection de vaccin Astra-Zeneca AZD1222 qui seront vaccinés avec une 2ème injection de vaccin ARNm Pfizer BNT162b2

1. Comparer la réponse immunitaire (humorale et cellulaire) obtenue avant et après la réalisation de la dose du vaccin BNT162b2.
2. Évaluer la réactogénicité clinique (locale et générale) après une injection du vaccin BNT162b2 administrée selon les recommandations en vigueur après une injection du vaccin AZD1222.

## **Inclusion criteria**

CRITERES D'INCLUSION DE LA COHORTE ADULTE :

Critères d'inclusion généraux communs à toutes les sous-populations :

- ? Avoir 18 ans ou plus
- ? Se faire vacciner contre la Covid-19 ou avoir déjà reçu une première ou deuxième injection de vaccin dans le cadre de la campagne nationale de vaccination
- ? Accepter les conditions de participation correspondant à chaque sous-population
- ? S'engager à respecter le calendrier des visites prévues dans le protocole de la recherche
- ? Prévoir de résider en France pendant au moins 2,5 ans à partir de l'inclusion
- ? Etre capable de donner seul son consentement libre, éclairé et écrit (au plus tard le jour de l'inclusion et avant tout examen/prélèvement) en signant le formulaire de consentement qui figure à la fin de ce document
- ? Etre affilié ou bénéficiaire d'un régime de sécurité sociale (l'Aide Médicale d'Etat n'est pas un régime de sécurité sociale)

Critères d'inclusion généraux des patients avec une condition chronique d'intérêt :

- ? Présenter au moins une pathologie listée dans la partie ci-dessus (chapitre 4)
- ? Si le participant participe à l'étude « Immunologie et virologie approfondies (IVA) », il ne devra présenter qu'une seule et unique pathologie d'intérêt listée

Critères d'inclusion spécifiques des sujets non atteints d'une des conditions chroniques d'intérêt ou autres pathologies / sous traitement ayant une influence connue sur la réponse immunitaire vaccinés avec une 1ère injection de vaccin Astra-Zeneca AZD1222 qui seront vaccinés avec une 2ème injection de vaccin ARNm Pfizer BNT162b2 :

- ? Personne ayant été vaccinée avec une première injection de vaccin Astra-Zeneca AZD1222 et qui sera vaccinée selon les recommandations en vigueur par une deuxième injection de vaccin à ARNm Pfizer BNT162b2.

## Critère d'inclusion commun au groupe contrôle :

? Etre indemne des conditions chroniques d'intérêt listées chapitre 4 et de toutes autres pathologies/sous traitement pouvant influencer la réponse immunitaire (pathologie auto-immune/inflammatoire ou déficit immunitaire non listés ci-dessus, insuffisance hépatique, prise de traitement immunosuppresseurs (incluant prise de corticostéroïdes oraux avec dose ? 10 mg/j équivalent Prednisone pendant plus de 15 jours), radiothérapie, dans les 6 mois précédent l'inclusion ou prévu pendant la durée de l'étude)

## CRITERES DE NON INCLUSION DE LA COHORTE ADULTE :

Critères de non inclusion généraux communs à toutes les sous-populations :

- ? Etre sous tutelle ou sous curatelle
- ? Etre une femme enceinte ou allaitante
- ? Présenter une contre-indication à la vaccination Covid-19 (liste non exhaustive : Présenter une allergie connue ou suspectée à l'un des composants du vaccin ; Avoir eu un contact à risque avec une personne Covid-19 confirmée dans les 7 derniers jours ; Avoir présenté des signes cliniques évocateurs de la Covid-19 dans les 7 derniers jours ; Présenter un épisode fébrile aigu à l'inclusion/vaccination ; Avoir reçu un vaccin autre que anti-Covid-19 dans les 15 derniers jours, ?)
- ? Avoir eu une infection Covid-19 documentée (exemple : sérologie SARS-CoV-2 positive connue avant l'inclusion, PCR ou test antigénique positif)
- ? Refuser que son NIR soit recueilli dans le but de consulter les bases de données de santé nationales SNDS/Data Health Hub
- ? Par mesure de sécurité, s'engager à ne pas entrer dans un essai clinique vaccinal pendant toute la période d'inclusion et de suivi dans la présente recherche ou toute autre recherche impliquant des prélèvements sanguins dont les volumes sanguins ajoutés à ceux prévus dans la cohorte ANRS0001S COV-POPART seraient incompatibles avec une RIPH2 (<https://www.legifrance.gouv.fr/loda/id/JORFTEXT000036805796>)

Critères de non inclusion spécifiques des PVVIH :

- ? Infection par le VIH-2
- ? Autres causes d'immunodépression : traitement par immunosuppresseurs ou biothérapies
- ? Infection opportuniste non contrôlée

Critères de non inclusion spécifiques au groupe contrôle :

- ? Etre atteint d'une ou plusieurs des conditions chroniques d'intérêt listées ci-dessus ou être concerné par toute autre pathologie ou tout traitement pouvant avoir une influence sur la réponse immunitaire (pathologie auto-immune/inflammatoire ou déficit immunitaire non listés ci-dessus, insuffisance hépatique, prise de traitement immunosuppresseurs (incluant prise de corticostéroïdes oraux avec dose ? 10 mg/j équivalent Prednisone pendant plus de 15 jours) ou radiothérapie dans les 6 mois précédent l'inclusion ou prévu pendant la durée de l'étude)
- ? Avoir une espérance de vie de moins de 2 ans

Une étude ancillaire pédiatrique a été intégrée au protocole COV-POPART, elle permet l'inclusion d'enfants et d'adolescents de 5 à 17 ans, selon les critères d'inclusion et de non inclusion spécifiques et définis dans le protocole volet pédiatrique.

**NOSO-COR PROJECT - MULTICENTER STUDY ON NOSOCOMIAL**

# TRANSMISSION OF SARS-COV2 VIRUS

Last update : 10/01/2021

Head :

Philippe VANHEMS , Laboratoire des Pathogènes Emergents, Fondation Mérieux, / Service Hygiène, Epidémiologie et Prévention

Responsible organization :

Hospices Civils de Lyon

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Describe and document suspected or confirmed cases of SARS-CoV2 nosocomial infections, their clinical spectrum and the determinants (risk factors / protection) at the participating hospitals.

## Inclusion criteria

Any voluntary adult or child or any healthcare workers from the study participant hospital who presents an infectious syndrome including the following definitions and oral/written informed consent obtained from parent/guardian for children < 18-years-old. (upon ethical requirements at each participant site).

Definitions

Suspect Case:

- Fever above 37.8 ° C if no antipyretics are taken; And or
- Cough or pharyngeal pain or other symptom suggestive of respiratory infection.

AND at least 1 of the following characteristics:

- return from a trip to China, or to a country in which the increase in the incidence of infections in SARS-CoV2 has been proven;
- close contact (sharing the same place of family, professional life, same plane, etc.) with a person defined as a suspected or confirmed case;
- Occurring in a hospital having received at least one suspected or confirmed case of SARS-CoV2 infection.

Confirmed Case

- The same clinical definitions, in addition to a positive RT-PCR-type virological diagnostic result specific to SARS-CoV2.

## COVIDOR - EPIDEMIOLOGICAL STUDY OF THE COVID-19 PRESTO TEST AMONG AGENTS OF THE LOCAL AUTHORITIES OF CCTVL, REGION CENTRE VAL DE LOIRE AND ORLEANS MÉTROPOLE. CORRELATION OF IGM LEVEL ACCORDING TO CONTACT WITH THE PUBLIC

Last update : 03/12/2021

Head :  
SERREAU Raphaël, PARADICT-O

Responsible organization :  
URC PARADICT-O

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

To collect health data about conditions workers and covid-19 serology status in Orleans Metropole, Loiret District and the Centre Val de Loire Region

## Inclusion criteria

Ages Eligible for Study: 18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Sampling Method: Non-Probability Sample

# NOSO-COR-IMMUNO - MULTICENTER STUDY ON NOSOCOMIAL TRANSMISSION OF SARS-COV2 VIRUS - ANCILLARY STUDY OF NOSO-COR PROJECT

Last update : 10/01/2021

Head :  
VANHEMS PHILIPPE, Laboratoire des Pathogènes Emergents / Service Hygiène, Epidémiologie, Infectiologie et Prévention

Responsible organization :  
Hospices Civils de Lyon

## Type of database

Bases de données issues d'enquêtes

## Study databases (details)

## Main objective

Le principal objectif de cette étude ancillaire est de décrire la réponse sérologique chez les personnes infectées par SARS-CoV-2 à distance de l'épisode infectieux.

Objectifs secondaires :

1. Caractérisation des populations T CD8 spécifiques du virus, phénotype et capacité fonctionnelle, présente dans la circulation (PBL)
2. Titration des anticorps neutralisants vs. facilitateurs

3. Comparaison des caractéristiques de la réponse immune mémoire des patients
4. Etude de la restauration immunitaire post-COVID19
5. Constitution d'une collection d'échantillons biologiques salivaires et sanguins aux HCL (serum et les cellules mononucléées du sang périphérique (PBMC)) et cession d'une partie des produits sanguins avant la fin de la recherche au Centre International de Recherche en Infectiologie (CIRI) pour initier des recherches pour de nouvelles connaissances scientifiques sur les agents pathogène SARS-CoV-2.

## Inclusion criteria

- ? Personnes incluses dans l'étude NOSO-COR présentant un diagnostic de COVID-19 confirmé par un test biologique RT-PCR sur écouvillon nasopharyngé spécifique pour le virus SARS-CoV-2
- ? Personnes majeures
- ? Personnes qui ont été dûment informées et qui ont signé le formulaire de consentement éclairé de l'étude ancillaire
- ? Personnes affiliées à un régime de sécurité sociale

# TREPID - ENQUÊTE TRAVAIL SOUS EPIDÉMIE

Last update : 03/26/2021

Head :  
ERB Louis

Responsible organization :  
Confédération général du Travail (CGT)

## Type of database

Bases de données issues d'enquêtes

## Study databases (details)

Etudes transversales non répétées (hors enquêtes cas-témoins)

## Main objective

Le syndicat des cadres et techniciens de la Confédération Générale du Travail (UGICT-CGT) s'est associé aux statisticiens syndiqués des services statistiques du ministère du Travail (Dares) et de la santé (Drees) pour piloter une enquête en ligne sur la situation professionnelle des salarié-es, l'enquête Travail sous épidémie (TrEpid).

Le questionnaire a été élaboré par des militant·es statisticien·nes travaillant au ministère des affaires sociales, experts dans les thématiques abordées. Dans la mesure du possible, les questions proviennent ou ont été adaptées à partir d'enquêtes portant le ?label de qualité statistique et d'intérêt général? décerné par le comité national de l'information statistique (Cnis).

Les individus sont interrogées sur leur situation professionnelle et personnelle, leur situation principale pendant le confinement (poursuite sur site, télétravail ou arrêt d'activité, ...). Des questions complémentaires portent sur les conditions de travail au sein de l'établissement.

L'échantillon recueilli pouvait induire des biais de sélection des répondant·es, dont les caractéristiques moyennes ne correspondaient pas à celles de l'ensemble de la population, comme par exemple les

travailleur·ses indépendants. Des méthodes statistiques ont été employées pour redresser la structure de l'échantillon (par genre, catégorie socio-professionnelle, type d'employeur et syndicalisation...) afin que celui-ci corresponde aux caractéristiques de la population française par application d'une méthode dite de calage sur marges.

Les témoignages présentés au fil de cette étude proviennent également des données récoltées par le dispositif d'enquête, en réponse à des questions ouvertes ou semi-ouvertes (sur le modèle « Autre : Précisez ? »).

## **Inclusion criteria**

Le questionnaire en ligne a été diffusé par les syndicats dans de nombreuses entreprises et administrations ainsi que relayé dans les réseaux sociaux et par différents médias nationaux. Sans prétention à l'exhaustivité ou à la représentativité parfaite, l'enquête a recueilli 24 000 réponses issues de milieux professionnels très divers.

# **RECOVER-19 - RÉHABILITATION FONCTIONNELLE ET RESPIRATOIRE ET SOIN NUTRITIONNEL DES PATIENTS ATTEINTS DE LA COVID-19**

Last update : 03/26/2021

Head :  
Alix Lilian

Responsible organization :  
CHU de Rennes

## **Type of database**

Autres

## **Main objective**

Déterminer l'efficacité d'un parcours de soins multidisciplinaire personnalisé (comportant une réadaptation à l'effort, une réhabilitation respiratoire si nécessaire et une stratégie thérapeutique nutritionnelle) sur la qualité de vie (composante physique du SF-36) des patients atteints de la COVID-19.

## **Inclusion criteria**

-Patient majeur défini comme cas confirmé de la COVID-19 ayant été hospitalisé ou non pour COVID-19

-Date du début des premiers symptômes de la COVID-19 ? 4 semaines et < 4 mois

-Patients présentant un déficit fonctionnel et/ou respiratoire et/ou une asthénie et/ou une dénutrition, persistant(s) au delà de 4 semaines des premiers symptômes de la COVID-19 :

o Augmentation du score de dyspnée de l'échelle mMRC ? 1 entre le mois précédent la COVID-19 et au-delà des 4 premières semaines post-COVID-19  
et/ou

o Score d'asthénie > 22 selon l'échelle de Pichot au-delà des 4 premières semaines post-COVID-19, en l'absence d'asthénie présente dans le mois précédent la COVID-19

(score d'asthénie selon l'échelle de Pichot <8)

et/ou

- o Perte de poids déclarée > 5% en moins de 6 mois, en comparant le poids minimum du patient au cours du mois précédent la COVID-19 et son poids au-delà des 4 premières semaines post-COVID-19 et/ou
- o IMC actuel < 20 (si âge < 70 ans) ou < 22 (si âge ≥ 70 ans) si l'IMC était ≥ 20 (si âge < 70 ans) ou ≥ 22 (si âge ≥ 70 ans) au cours du mois précédent la COVID-19

## **COVID-PRO-IMPACT - IMPACT OF THE COVID-19 PANDEMIC ON THE PSYCHOLOGICAL QUALITY OF LIFE OF HEALTHCARE PROFESSIONALS**

Last update : 04/15/2021

Head :

CHENE Gautier, Hôpital Femme Mère Enfant

Responsible organization :

Hospices Civils de Lyon

### **Type of database**

Study databases

### **Study databases (details)**

Cohort study

### **Main objective**

Study the evolution of the psychological quality of life of healthcare professionals during the confinement period linked to the COVID-19 pandemic

### **Inclusion criteria**

person over 18

person exercising a profession in the field of health

person who expressed his non-opposition

## **CONFIMIDS - EVALUATION OF THE IMPACT OF THE LOCKDOWN AND EASING OF RESTRICTIONS ON THE MANAGEMENT OF PATIENTS WITH INFLAMMATORY DISEASE AND IMMUNE DISORDERS FOLLOWED UP AS PART OF THE FHU IMMINENT PROJECT (RHEUMATOLOGY, DERMATOLOGY, INTERNAL MEDICINE, PULMONOLOGY, GASTROENTEROLOGY AND NEUROLOGY)**

Last update : 05/05/2021

Head :

DEZOTEUX Frédéric, INSERM U1286 INFINITE

Responsible organization :

Lille University Hospital

## Type of database

Study databases

## Study databases (details)

### Main objective

Estimate the frequency of patients, with chronic inflammatory disorders, followed up as part of the FHU IMMINeNT project (gastroenterology, rheumatology, dermatology, pulmonology, neurology, internal medicine), whose follow-up has been affected by the lockdown and easing of restrictions.

### Inclusion criteria

All adult patients followed up as part of the FHU project for:

- Chronic inflammatory bowel disease or IBD (Crohn's disease and ulcerative colitis),
- Rheumatic disorders (rheumatoid arthritis and spondyloarthritis)
- Multiple sclerosis
- Asthma
- Psoriasis
- Atopic dermatitis
- Systemic auto-immune disease (scleroderma and lupus)

## CORANGE - STUDY OF THE SEROPREVALENCE OF CORONAVIRUS IN AN ORANGE EMPLOYEE POPULATION

Last update : 05/06/2021

Head :

GOUYET Thomas

Responsible organization :

Orange SA

## Type of database

Study databases

## Study databases (details)

Longitudinal study (except cohorts)

### Main objective

The primary objective of the study is to determine serological status for coronavirus on a sample based on an Orange employee population.

### Inclusion criteria

All Orange employees, volunteering to take part in the study. - Aged 18 years or over on the day of enrolment

## CORHUM - MORBIDITY-MORTALITY OF COVID-19 IN PATIENTS

# **WITH CHRONIC RHEUMATIC DISORDER TREATED WITH IMMUNOSUPPRESSANTS**

Last update : 05/05/2021

Head :

LETAROUILLY Jean-Guillaume

Responsible organization :

Lille University Hospital

## **Type of database**

Study databases

## **Study databases (details)**

Not-repeated cross-sectional studies (except case control studies)

## **Main objective**

Estimate morbidity-mortality associated with COVID-19 in patients with chronic rheumatic disorder (CRD) receiving immunosuppressants (IS).

## **Inclusion criteria**

Patients with RA on csDMARD +/- bDMARD or tsDMARD +/- corticosteroid therapy fulfilling 2010 ACR/EULAR classification criteria? Patients with SpA receiving bDMARD or tsDMARD +/- csDMARD +/- non-steroidal anti-inflammatory drugs fulfilling ASAS classification criteria? Patients with SLE receiving hydroxychloroquine +/- csDMARD +/- corticosteroid therapy +/- bDMARD fulfilling 2019 ACR/EULAR classification criteria

# **COROFET - CLINICAL AND LABORATORY EPIDEMIOLOGICAL MONITORING OF PREGNANT WOMEN WITH EVALUATION OF THE OBSTETRIC, FOETAL AND NEONATAL RISK ASSOCIATED WITH SARS-COV-2 DURING THE COVID-19 PANDEMIC- COROFET**

Last update : 05/05/2021

Head :

DUBUCS Charlotte, IUCT-Oncopole Pathology Department

Responsible organization :

Toulouse University Hospital

## **Type of database**

Others

## **Main objective**

In this situation in which data are crucial to understanding the effects of SARS-CoV-2 in the pregnant female population, our primary objective is to collect clinical and paraclinical data from a large sample of

women recruited from our level 3 maternity unit, and to create biological and tissue collections with a view to responding to a series of questions, partly explained in the research programme, but which may also evolve as knowledge progresses.

### **Inclusion criteria**

Adult females aged 18 years or over at the date of inclusion

Pregnant women giving birth at the Paule de Viguier maternity unit, Toulouse University Hospital, in the study, between April 2020 and April 2021, regardless of pregnancy outcome (live births, intrauterine foetal death, termination of pregnancy, i.e. miscarriages, medical termination of pregnancy) and term

Women having given their consent to take part in the study

Women registered with a social security scheme (including the state welfare scheme)

## **COV1APHP - COLLECTION OF BLOOD SAMPLES FROM INDIVIDUALS HAVING DEVELOPED SARS COV-2 INFECTION**

Last update : 04/23/2021

Head :

Launay Odile

Responsible organization :

BIOMERIEUX

### **Type of database**

Health relevant administrative databases

### **Main objective**

This study aims to develop prototype tests for the in vitro diagnostic serology of SARS-CoV-2

### **Inclusion criteria**

Healthcare personnel or patient, having recovered from COVID-19

Individuals having developed typical symptoms of SARS-CoV-2, with a result confirmed by a PCR laboratory test on a nasopharyngeal swab, and with a blood sample taken at least 10 days after onset of symptoms

Adults

Individuals having been duly informed and signed the informed consent form

Affiliated with a French social security system

## **COV-ACTIVITÉ - IMPLEMENTATION AND EFFECT OF IMPLEMENTING PHYSICAL ACTIVITY PROGRAM AMONG OLDER ADULTS IN HOSPITALIZED POSITIVE COVID-19 OLDER ADULTS**

Last update : 05/05/2021

Head :

ROLLAND Yves

Responsible organization :

Toulouse University Hospital

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Describe the feasibility of an unsupervised physical activity exercise programme for adults aged 75 years and over, hospitalised in covid-19 unit

## Inclusion criteria

75 years and over

COVID-19 positive on molecular diagnosis (PCR) or highly probable diagnosis by CT scan

Hospitalised in the geriatric post-emergency department (COVID unit), Rehabilitation Unit (Toulouse), Grenoble geriatric department and Guadeloupe University Hospital

Patient able to perform all tests

# COVIDET - EVALUATION OF SARS-COV-2 SEROPREVALENCE AMONG PRISON INMATES

Last update : 05/05/2021

Head :

Mellan Guillaume

Responsible organization :

AP-HP

## Type of database

Study databases

## Study databases (details)

## Main objective

Evaluate the prevalence of SARS-CoV-2 infection among prison inmates in detention institutions in the Ile-de-France region, by measuring SARS-CoV-2 antibody levels in plasma

## Inclusion criteria

Subjects fulfilling all of the following criteria will be included in the study:

- o Female inmates on the lists provided by the detention institutions or male inmates randomly selected from the lists provided by the detention institutions.
- o Aged 18 to 80 years.
- o Freely given, informed consent form signed.

# COVIDIV - COLLATERAL DAMAGE OF THE COVID-19 PANDEMIC OBSERVED AMONG PATIENTS RECEIVING TREATMENT WITH INTRAVITREAL (IVT) INJECTIONS OF ANTIANGIOGENIC AGENTS

Last update : 04/23/2021

Head :  
Mauget-Faÿsse Martine

Responsible organization :  
Foundation A. de Rothschild Hospital/Clinical Research Unit

## Type of database

Others

## Main objective

Describe the changes in visual acuity among patients receiving treatment with repeat IVT injections of antiangiogenic agents during the COVID-19 epidemic, between September 2019 and May 2021

## Inclusion criteria

Patient aged 18 years and over

- Eye disorder requiring treatment with repeat IVT injections of antiangiogenic agents: Exudative ARMD, macular oedema associated with diabetes or secondary to retinal vein occlusion.
- Initiation of treatment with repeat IVT injections before 01/10/2019

# COVIDONNEUR - SARS-COV-2 SEROPREVALENCE STUDY IN THE BLOOD DONOR POPULATION

Last update : 05/06/2021

Head :  
Gallian Pierre, Emerging Viruses Units, 20-21 Boulevard Jean Moulin, 13005 Marseille

Responsible organization :  
French National Blood Service (EFS)

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Estimate the seroprevalence of SARS-CoV-2 infection in the French blood donor population (18-70 years) in different geographical zones (mainland France and overseas departments), at different times in the epidemic, so as to model the progression of the epidemic

## Inclusion criteria

Accepted blood donors  
aged 18 to 70 years.  
in the geographical zones of interest

having agreed to the use of their samples for research

Plasma samples > 500 µL in volume

## **COVI-ST - LONGITUDINAL FOLLOW-UP OF THE RISK OF EXHAUSTION, ANXIETY AND QUALITY OF LIFE OF HOSPITAL STAFF IN THE CONTEXT OF THE COVID-19 PANDEMIC**

Last update : 05/05/2021

Head :

Guinot Isabelle

Responsible organization :

Métropole Savoie Hospital (CHMS)

### **Type of database**

Study databases

### **Study databases (details)**

Cohort study

### **Main objective**

Evaluate the impact of the COVID-19 pandemic on burn-out 2 years after the "CHMS Emergency Response Plan (Plan Blanc)", i.e. as of 06/07/2022

### **Inclusion criteria**

Volunteer hospital staff, having worked at CHMS during the Emergency Response Plan for the COVID-19 pandemic, i.e. from 17/03/2020 to 05/07/2020

- Aged >18 years,
- Not under legal protective measures
- Professional having given free, informed confirmation of their non-objection to taking part in the study

## **COVITREM-1 - PROGNOSTIC VALUE OF MEASURING THE ACTIVATION PATHWAY FOR TRIGGERING RECEPTOR EXPRESSED ON MYELOID CELLS-1 (TREM-1) IN PATIENTS HOSPITALISED DUE TO COVID-19**

Last update : 05/06/2021

Head :

GIBOT Sébastien

Responsible organization :

Nancy Regional University Hospital

### **Type of database**

Study databases

## **Study databases (details)**

Cohort study

### **Main objective**

Evaluate the prognostic value of initial TREM-1 activation (first measurement collected) on clinical deterioration in patients hospitalised due to COVID-19 in medical, emergency and intensive care departments

### **Inclusion criteria**

Patients aged over 18 years

Hospitalised for less than 3 days for any reason whatsoever, but screened for Covid-19. SARS-CoV-2 infection should be "probable" or "confirmed" according to the definition published on 3 April by Santé Publique France (French Public Health Agency): laboratory confirmation (by positive RT-PCR further to nasopharyngeal sample or any other sample and/or positive serology indicating infection) or by a composite endpoint combining characteristic pulmonary impairment upon imaging and clinical/laboratory effects suggesting viral infection (including: fever, cough, chest pain, and biological inflammatory syndrome, lymphopenia, elevated liver enzymes).

Registered with a social security scheme or a beneficiary of such a scheme

The patient or their representative will have received information on the study and signed the emergency informed consent/inclusion form in compliance with Article L.1122-1-3 of the French Public Health Code (CSP)

## **EDIFICE - OBSERVATIONAL STUDY ON THE DIAGNOSTIC EVALUATION OF THE INTESTINAL MICROBIOTA OF FRENCH PEOPLE INFECTED WITH THE CORONAVIRUS**

Last update : 05/05/2021

Head :

MARTI Guy

Responsible organization :

LUXIA SCIENTIFIC

### **Type of database**

Others

### **Main objective**

Validate the hypothesis for a relationship between the loss of diversity of the intestinal microbiota and screening positive for COVID-19, by comparing hospitalised COVID-19 positive patients with an exposed French population represented by hospital medical and paramedical personnel

### **Inclusion criteria**

COVID-19 positive patients: hospitalised patients diagnosed with COVID-19 in one of the two investigating sites, and able to provide a stool sample

Exposed subjects: Medical and paramedical personnel working at one of the two investigating sites, having been in direct contact with the patients.

Aged between 18 and 85 years

Subjects able to read the French-language study information leaflet

Patients with social cover

## **FILO-COVIM - OBSERVATIONAL STUDY ON THE IMPACT OF THE COVID-19 EPIDEMIC ON PATIENTS WITH MYELOPROLIFERATIVE NEOPLASMS**

Last update : 04/23/2021

Head :

KILADJIAN Jean-Jacques, CIC 1427

Responsible organization :

FILO "French Innovative Leukemia Organization"

### **Type of database**

Study databases

### **Study databases (details)**

Cohort study

### **Main objective**

Describe the rate of serious Coronavirus infections in the different subgroups of patients with myeloproliferative neoplasms defined by ongoing treatment during the epidemic.

### **Inclusion criteria**

Male or female aged 18 years and over

Male or female patient with PV, ET, PMF or MF secondary to PV or ET diagnosed before the COVID-19 pandemic

Attending an appointment from April 2020

## **LICORNE - PREDICTIVE FACTORS FOR MORTALITY AT D28 FOR PATIENTS MANAGED AT LILLE UNIVERSITY HOSPITAL FOR COVID-19**

Last update : 05/05/2021

Head :

CHOPIN Marie Charlotte

DEPLANQUE Dominique

Responsible organization :

Lille University Hospital

### **Type of database**

Others

### **Main objective**

The primary objective of this study is to identify the predictive factors for mortality at D28 of SARS-CoV-2 infection in patients managed for COVID-19 at Lille University Hospital, via the creation of an epidemiological, clinical, biological, immunological, genetic, microbiological, pathological, radiological and therapeutic database, indicating the results of functional tests.

NB: The analysis will exclude patients who are "confirmed cases" with serious SARS-CoV-2 infection managed in a conventional medicine department owing to the therapeutic limitations (TL) which existed prior to SARS-CoV-2 infection, due to incurable disease or underlying comorbidities.

### **Inclusion criteria**

Any adult patient, "suspect patients", "possible cases", "probable cases" or "confirmed cases" of SARS-CoV-2 infection admitted to Lille University Hospital.

## **NICORISCOVID - MEASUREMENT OF THE STRENGTH OF THE RELATIONSHIP BETWEEN TOBACCO USE AND THE RT-PCR TEST FOR SARS-COV2**

Last update : 05/05/2021

Head :

KARMOCHKINE Marina, no

Responsible organization :

AP-HP

### **Type of database**

Study databases

### **Study databases (details)**

Case control study

### **Main objective**

Measure the strength of the relationship between tobacco use and the RT-PCR test for SARS-CoV2

### **Inclusion criteria**

Care personnel having attended the Hôtel-Dieu Hospital Covid screening centre for symptoms compatible with SARS-CoV2 infection,

-Aged over 18 years,

With an email address,

-Able to express non-objection (=questionnaire feedback

## **SARCODO - EVALUATION OF COAGULOPATHY AND ENDOTHELIAL DYSFUNCTION AS A PREDICTIVE FACTOR FOR THE SEVERITY OF SARS-COV-2/COVID-19 INFECTION**

Last update : 05/05/2021

Head :

SMADJA David, UMR-S1140 and Biosurgical Research Laboratory (Carpentier Foundation)

Responsible organization :  
AP-HP

## Type of database

Others

## Main objective

Study the coagulopathy, vascular lesion and markers for tissue distress to characterise the exacerbation of patients with COVID-19 and identify patient populations who will develop or experience exacerbation of a thromboembolic or microvascular process, but also require curative anticoagulation.

## Inclusion criteria

Patients aged at least 18 years

Hospitalised in an intensive care or medicine department for suspected COVID-19.

Patients covered by a social security regime (other than the state welfare scheme)

Patient having been informed of the study and having given their informed consent in writing, or for whom a family member/trusted person has given their agreement

# SISCOVID - OBSERVATIONAL, PROSPECTIVE, MULTICENTRE COHORT OF PATIENTS FOLLOWED UP AFTER HOSPITALISATION TO EVALUATE RESPIRATORY SEQUELAE SUBSEQUENT TO SARS-COV-2 (COVID-19) INFECTION

Last update : 05/03/2021

Head :  
CALCAIANU George

Responsible organization :  
GHRMSA health institution

## Type of database

Others

## Main objective

Evaluate the respiratory sequelae after SARS-CoV-2 infection in patients hospitalised for severe COVID-19 pneumonia requiring O2, with subsequent outpatient follow-up (6 months) by:

- Low-dose chest CT scan (LD-chest CT),
- Static lung function tests (LFT),
- Arterial blood gases in ambient air at rest (AA BG) and/or with oxygen (O2 BG),
- 6-minute walking test in ambient air (6WT AA) and/or with oxygen (6WT O2)

## Inclusion criteria

Patient having received verbal information and not objecting to the study

Age >= 18 years inclusive

Patient hospitalised for severe COVID-19 pneumonia requiring O2

Patient having contracted SARS-CoV-2 infection proven by RT-PCR and/or retrospective serology and/or

COVID-19 syndrome with chest CT scan consistent with infection (over the period from 1 March 2020 to 30 June 2020)

## **CERTIFY.HEALTH - EVALUATION OF THE CERTIFY.HEALTH APPLICATION AS A DIGITAL RESOURCE FOR MANAGING THE COVID-19 PANDEMIC**

Last update : 05/05/2021

Head :

BOSSON Jean-Luc, TIMC Laboratory - Themas team

Responsible organization :

TIMC-IMAG Laboratory - Grenoble Alpes University

### **Type of database**

Study databases

### **Study databases (details)**

Longitudinal study (except cohorts)

### **Main objective**

Evaluate the user-friendliness and acceptability of the Certify.Health application among healthcare personnel in healthcare, research and teaching facilities

### **Inclusion criteria**

- Age ≥ 18 years
- Healthcare personnel in healthcare, research and teaching facilities, or a member of the home-care network:
  - ? equipped with a smartphone which can run the electronic application (version of the participant's Android or iOS operating system compatible with the application) and having an internet connection OR a computer with internet access
  - ? agreeing to provide their mobile phone number to access the application and receive notifications
- OR a resident in a selected nursing home

## **COMCOR - STUDY OF SOCIODEMOGRAPHIC FACTORS, BEHAVIOURS AND PRACTICES ASSOCIATED WITH SARS-COV-2 INFECTION (COMCOR)**

Last update : 05/07/2021

Head :

Fontanet Arnaud, Emerging Diseases Epidemiology Unit

Responsible organization :

Institut Pasteur

### **Type of database**

Study databases

## **Study databases (details)**

Case control study

## **Main objective**

Identify the sociodemographic characteristics, places frequented, and behaviours associated with a risk of SARS-CoV-2 infection.

## **Inclusion criteria**

All subjects:

- o Adult subject
- o Having agreed to take part in the study
- o Index case:
  - o Cases identified in the COVID-19 screening information system database, SIDEP
  - o With a positive test for SARS-CoV-2 by RT-PCR on a nasopharyngeal or throat swab (or any other sample for which current technology indicates active infection if positive) within the past 14 days
- o Close contact cases:
  - o Living in the same household (sharing the same home) as the case having invited him/her to take part
  - o With a positive test for SARS-CoV-2 by RT-PCR on a nasopharyngeal or throat swab (or any other sample for which current technology indicates active infection if positive) following contact with the index case
- o Close contact controls:
  - o Living in the same household (sharing the same home) as the case having invited him/her to take part
  - o With a negative test for SARS-CoV-2 by RT-PCR on a nasopharyngeal or throat swab (or any other sample for which current technology indicates active infection if positive) following contact with the index case
- o Distant contact controls:
  - o Selected by IPSOS based on criteria including age, gender, and administrative department of residence (paired with index cases)

## **SAPRIS-SERO - HEALTH, PERCEPTION, PRACTICES, AND SOCIAL RELATIONS AND INEQUALITIES AMONG THE GENERAL POPULATION DURING THE COVID-19 CRISIS - SEROLOGY (SAPRIS-SERO).**

Last update : 05/05/2021

Head :

CARRAT Fabrice, IPLESP - U1136

ZINS Marie, UMS 11

SEVERI Gianluca, CESP UMR U1018

CHARLES Marie-Aline, UMS Ined Inserm Elfe

ANCEL Pierre-Yves, CRESS UR1153

TOUVIER Mathilde, CRESS-EREN UMR U1153 Inserm

Responsible organization :

Inserm

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Based on the collection of capillary blood samples taken by the subjects, SAPRIS-SERO will help to:

- Estimate the cumulative incidence of infection in the general population (objective 1a),
- Characterise the “immune” portion of the population and the durability of immunity (objective 1b).

## Inclusion criteria

Be a participant in one of the cohorts involved in the SAPRIS project, or a person sharing the same accommodation

# COVID-OISE - LONGITUDINAL FOLLOW-UP OF A POPULATION-BASED COHORT IN A FRENCH TOWN WITH INTENSE SARS-COV-2 CIRCULATION IN EARLY 2020.

Last update : 05/05/2021

Head :

FONTANET Arnaud, Emerging Diseases Epidemiology Unit

Responsible organization :

Institut Pasteur

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Study the changes over time of the specific humoral response generated by SARS-CoV-2 virus infection in different biological specimens from subjects in different age groups.

## Inclusion criteria

1. Person living, working or studying in Crépy-en-Valois or in the surrounding towns  
OR in the same household as one of the above persons  
OR professional, resident or patient in retirement homes or the Saint-Lazare Hospital long-stay healthcare facility, in Crépy-en-Valois
2. Adult or minor subject from 5 years of age
3. Individual covered by a social security scheme
4. Individual having given their consent to take part in the study after reviewing the information provided by a qualified person representing the principal investigator

## **EPIC - DESCRIPTIVE, PROGNOSTIC STUDY OF SARS-COV-2 CORONAVIRUS INFECTION IN MARTINIQUE, CONDUCTED IN A HOSPITAL COHORT OF PATIENTS WITH PROBABLE OR CONFIRMED COVID-19 INFECTION**

Last update : 05/07/2021

Head :

CABIEChabartier AndréCyrille, French West Indies - Guiana CIC - Inserm 1424 - Infectious, genetic and emerging diseases in tropical regions

Chabartier Cyril

Responsible organization :

Martinique University Hospital

### **Type of database**

Others

### **Main objective**

Identify the demographic, clinical, biological, virological and immunological factors associated with, or predictive of the onset of a severe form of COVID-19 in a cohort of children and adults managed in a hospital setting at Martinique University Hospital.

### **Inclusion criteria**

Inclusion criterion: Patient hospitalised in a COVID-specific treatment unit, including intensive care, for possible or confirmed SARS-CoV-2 infection (PCR+ and/or CT scan consistent with infection) at Martinique University Hospital.

Exclusion criterion: Refusal to take part, by the patient or their legal representative

Exclusion criteria: patient with confirmed diagnosis of infection with a pathogen other than SARS-CoV-2, and no likelihood of co-infection with SARS-CoV-2

## **REHABCOVID - ORGANISATION OF RESPIRATORY REHABILITATION IN POST-COVID-19 PATIENTS WITH SEQUELAE. EVALUATION AND THERAPEUTIC INDICATION FOR REMOTE REHABILITATION VS. CONVENTIONAL REHABILITATION.**

Last update : 04/23/2021

Head :

Vallier Jean-Marc

Responsible organization :  
Toulon Intermunicipal Hospital - La Seyne sur Mer

## Type of database

Others

## Main objective

Compare the efficacy of two respiratory rehabilitation methods on patient physical capacity: a 4-week remote respiratory rehabilitation (RRR) programme vs. a conventional respiratory rehabilitation (RR) programme, for reducing sequelae present in post-COVID-19 patients.

## Inclusion criteria

1. Subjects aged over 18 years.
2. Subjects having contracted COVID-19 determined by a positive RT-PCR test and/or presence of antibodies.
3. Subjects having received a medical prescription for respiratory rehabilitation.
4. Subjects equipped with the necessary computer equipment and network coverage for videoconferencing.
5. Subjects with at least one of the following post-COVID-19 sequelae:
  - Dyspnoea at rest or on exertion measured using the mMRC (modified Medical Research Council) scale, with a score greater than or equal to 2. (Vestbo et al., 2013)
  - Hyperventilation measured using the Nijmegen questionnaire, with a score greater than or equal to 23/64 (Van Dixhoorn and Duivenvoorden, 1985; Sauty and Prosper, 2008)
  - Exercise intolerance measured using the 1 min-STS (1-minute sit-to-stand test) according to the standards based on age and gender, established by Strassmann et al. (2013).
  - Abnormal fatigue measured using the MFI-20 (Multidimensional Fatigue Inventory), French-language version validated by Gentile et al. (2003) according to the standards based on age and gender, established by Schwarz et al. (2003).
  - Anxiety and depression status measured using the HADS (Hospital Anxiety and Depression scale), French-language version validated by Roberge et al. (2013) according to the standards based on age and gender, established by Bocéréan and Ducret (2014)
6. Registered with or a beneficiary of a social security scheme.

## CONFINS - CONFINS

Last update : 04/23/2021

Head :

Tzourio Christophe, Bordeaux Population Health UMRS 1219  
Schück Stéphane

Responsible organization :  
University of Bordeaux, Kappa Santé, Kapcode

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Describe the mental health impact of the lockdown and Covid-19 pandemic, along with its progression over time.

Secondary objectives:

- Identify profiles at risk of psychiatric disorders.
- Evaluate the standard of health literacy and ability to identify fake news.
- Study the portrayals and knowledge of vaccines.

## Inclusion criteria

Adults (+18), locked down in France at the time of inclusion.

# SUIVI-COVID - EVALUATION OF THE POST-COVID-19 FUNCTIONAL STATUS (PCFS) SCALE AS A SCREENING TOOL FOR SEQUELAE IN PATIENTS WITH COVID-19 HYPOXIC PULMONARY DISEASE

Last update : 04/23/2021

Head :

Eschapasse Emmanuel

Responsible organization :

Nantes University Hospital

## Type of database

Others

## Main objective

The primary objective of this project is to propose a French translation and assess the “post-COVID-19 functional status” (PCFS) scale as a screening tool for respiratory sequelae in patients with COVID-19 hypoxic pulmonary disease after 3 months in the Nantes COVID-19 hypoxic pulmonary disease cohort, attending an appointment at Nantes University Hospital. The primary endpoint will be to assess the Spearman correlation between the PCFS scale and the mMRC (modified Medical Research Council) scale.

## Inclusion criteria

Adult patient, aged under 75 years, having been admitted to Nantes University Hospital for hypoxic pulmonary disease, defined by the need for supplemental oxygen therapy for at least 24 hours, associated with a diagnosis of SARS-CoV-2 infection confirmed by PCR or CT scan lesions consistent with infection in the event of a negative PCR, attending the 3 month follow-up visit, and having completed the PCFS and mMRC questionnaires.

# PEDONCOVID - SFCE NATIONAL COHORT ON SARS-COV-2 (COVID-19) INFECTIONS IN PAEDIATRIC ONCOLOGY-HAEMATOLOGY

Last update : 05/05/2021

Head :  
ROUGER-GAUDICHON Jérémie

Responsible organization :  
CHU Caen Normandie

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

Describe the presentation and clinical course of SARS-CoV-2 infection among patients followed up in a paediatric oncology-haematology department or young adult and adolescent unit at an SFCE centre, for cancer or a benign tumour treated with chemotherapy, radiotherapy or targeted therapy.

## Inclusion criteria

Children and legal representatives, or adult patients having received information on the study  
AND

- Patient followed up in a paediatric oncology-haematology department or young adult and adolescent unit at an SFCE centre for cancer or a benign tumour treated with chemotherapy, radiotherapy or targeted therapy, with a cancer treatment either ongoing or completed within the past 6 months, or a history of allogeneic haematopoietic stem cell transplantation with immunosuppressant therapy ongoing or discontinued within the past 6 months, or a history of CAR-T cell therapy

AND

- Diagnosis of SARS-CoV-2 infection confirmed by PCR or positive IgM serology

OR

- Clinical and radiological diagnosis characteristic of SARS-CoV-2 infection without confirmation of infection by PCR or positive IgM serology with:

o Presence of at least 2 of the following signs in the event of contact with a subject currently presenting SARS-CoV-2 positive infection, or 3 of the following signs in the absence of contact: fever, cough, dysgeusia, dysosmia, myalgia, chest pain, dyspnoea, signs of respiratory distress, rhinorrhoea or nasopharyngeal congestion, diarrhoea, headaches, recent onset or exacerbation of asthenia and rash.

AND

o One or more radiological abnormalities observed on chest CT scan compatible with a diagnosis of COVID-19: peripheral and/or subpleural and/or bilateral ground-glass opacities, intralobular thickening with a "crazy-paving" appearance, linear condensations with or without peripheral halo (reverse halo sign).

## DÉNUTCOVID - NUTRITIONAL EVALUATION OF COVID PATIENTS HOSPITALISED IN THE COVID UNITS AT ST VINCENT HOSPITAL.

Last update : 05/07/2021

Head :  
Dr Cortet Arnaud

Responsible organization :

**Type of database**

Others

**Main objective**

Evaluate the initial nutritional status of COVID patients hospitalised in standard COVID units (not in intensive care units).

**Inclusion criteria**

Inclusion criteria:

- o Patient admitted to a standard hospital department within the past 72 hrs,
- o Age > 18 years,
- o Covid-19 diagnosis confirmed by positive RT-PCR
- o Patient agreeing to take part in the study
- o Patient registered with a social security scheme

Exclusion criteria:

- o Prior hospitalisation in critical care (intensive care unit) for more than 72 hours due to the risk of biased nutritional status analysis.

## CANNAVID - STUDY ON THE IMPACT OF COVID-19 ON USE, PRACTICES AND HEALTH AMONG REGULAR CANNABIS USERS

Last update : 05/06/2021

Head :

Roux Perrine , UMR 1252 SESSTIM

Responsible organization :

Bus 31/32 Association (CSAPA, CAARUD)

**Type of database**

Study databases

**Study databases (details)**

Repeated cross-sectional studies (except case control studies)

**Main objective**

Evaluate the impact of the different lockdowns on cannabis use practices among daily users, psychoactive substance use and the onset of related symptoms (withdrawal, pain, sleep disorders, anxiety, depression).

**Inclusion criteria**

- Daily cannabis users or individuals having taken part in the previous CANNAVID series for questionnaires completed from the second lockdown;
- Aged over 18 years;
- Able to understand French;
- Residing in France;

Agreeing to take part in the study and having expressed their non-objection.

## **ECHO - PERCEPTIONS AND IMPACT OF THE COVID-19 EPIDEMIC IN HOUSING FACILITIES FOR SOCIALLY EXCLUDED INDIVIDUALS**

Last update : 05/05/2021

Head :

MELCHIOR Maria, Pierre Louis Institute for Epidemiology and Public Health/Inserm UMR\_S 1136  
DUCARROZ Simon, Research on Healthcare Performance (RESHAPE) INSERM U1290

Responsible organization :

Pierre Louis Institute for Epidemiology and Public Health (IPLESPI)/Inserm UMR\_S 1136

### **Type of database**

Study databases

### **Study databases (details)**

Repeated cross-sectional studies (except case control studies)

### **Main objective**

Describe the state of health, knowledge, perceptions and practices relating to COVID-19 infection and its prevention, among vulnerable individuals housed in facilities run by associations

### **Inclusion criteria**

Population inclusion criteria:

- aged over 18 years
- not presenting any cognitive impairment or learning disorders
- residing in housing facilities
- in the Ile-de-France, Lyon and Strasbourg regions

## **COVIPACT - IMPACT OF THE COVID-19 EPIDEMIC ON PATIENT MANAGEMENT IN THE ONCOLOGY-HAEMATOLOGY SETTING, AND ON PSYCHOLOGICAL REPERCUSSIONS AMONG PATIENTS AND CAREGIVERS**

Last update : 04/30/2021

Head :

FAVEYRIAL Audrey

Responsible organization :

FRANCOIS BACLESSE CENTRE

### **Type of database**

Others

### **Main objective**

Evaluate the impact of the COVID-19 pandemic on adjustments to medical cancer treatment delivered in the outpatient setting to patients with cancer or haematological malignancies undergoing treatment.

### **Inclusion criteria**

- Adult patient, treated for a solid tumour or haematological malignancy
- Receiving or needing to receive medical cancer treatment delivered in an outpatient oncology setting at participating sites: treatment initiated before or during the COVID-19 pandemic
- The patient does not object to taking part in the study
- Patient not deprived of their liberty or under supervision
- Female patient with no associated geographical, social or psychopathological condition liable to compromise the patient's ability to take part in the study

## **COV-JEUNENFANT - EXPERIENCE OF FAMILIES WITH YOUNG CHILDREN (FROM BIRTH TO 6 YEARS OF AGE) DURING THE FIRST LOCKDOWN**

Last update : 05/05/2021

Head :

ZAOUCHE GAUDRON Chantal, Scientific interest group on infants, early childhood in context (BECO) - Toulouse Midi-Pyrénées Federal University

Responsible organization :

Toulouse Midi-Pyrénées Federal University

### **Type of database**

Study databases

### **Study databases (details)**

### **Main objective**

Describe the experience of mothers, fathers and their young children before the end of the first lockdown, what they perceived as the best and worst moments during the health crisis, and shed light on the most widely used activities, possibly gender- and socially-based, and which emerge from household chores (home-schooling, care, upkeep) together with the associated emotions for each parent. The analyses are compared based on demographic and socioeconomic variables (gender, age, level of education, accommodation, employment, etc.).

### **Inclusion criteria**

- Adult (age? 18 years)
- With at least one child under 6 years of age
- Residing in France
- Having spent the whole lockdown (17 March to 11 May 2020) in France

## **SERODRON - EVALUATION OF HEALTHCARE PROFESSIONAL EXPOSURE TO COVID-19**

Last update : 05/06/2021

Head :

PATOZ Pierre

Responsible organization :  
Tourcoing Hospital

## Type of database

Others

## Main objective

Determine the prevalence of SARS-CoV-2 antibodies among hospital staff

## Inclusion criteria

Inclusion

- Personnel working in the healthcare institution
- Eligible for sampling
- Registered with or a beneficiary of a social security scheme

Non-inclusion

- Minor patient
- Refusal to take part
- Guardianship
- Curatorship

# COCO\_LATE - CLINICAL EVENTS OCCURRING WITHIN 6 MONTHS OF SARS-COV-2 INFECTION: MULTICENTRE COHORT

Last update : 05/06/2021

Head :

ROBINEAU Olivier

Responsible organization :  
Tourcoing Hospital

## Type of database

Others

## Main objective

Describe, over time, the symptoms presented by patients reporting persistent symptoms (more than two months after onset) or onset of symptoms more than 3 weeks after the beginning of symptomatic SARS-CoV-2 (COVID-19) infection evidenced by laboratory tests.

## Inclusion criteria

1- History of symptomatic SARS-CoV-2 infection defined by:

A positive RT-PCR result for SARS-CoV-2 OR positive SARS-CoV-2 serology combined with at least one event:

- Anosmia occurring after February 2020
- OR CT scan consistent with COVID-19

- OR ? 2 symptoms coinciding with the virology sample, including: asthenia, cough, dyspnoea, fever, myalgia, dysgeusia, diarrhoea AND not present prior to diagnosis
- 2- AND persistence of at least one symptom present in the first 3 weeks of COVID-19, more than 8 weeks after the first COVID symptoms
- OR late onset of at least one new symptom at least 3 weeks and not more than 6 months after the first symptoms of SARS-CoV-2 infection
- 3- First symptoms within the past 6 months on the date of inclusion
- 4- Beneficiary of a health insurance scheme or the state welfare scheme
- 5- Having signed an informed consent form at inclusion

## **PRECARES - "POVERTY AND COVID-19: CHANGES IN ACCESS AND RECOURSE TO HEALTH CARE", ÎLE-DE-FRANCE MARCH-JUNE 2020**

Last update : 05/05/2021

Head :

Véran Jean François

Responsible organization :

Doctors without Borders (MSF)

### **Type of database**

Study databases

### **Study databases (details)**

Not-repeated cross-sectional studies (except case control studies)

### **Main objective**

The study set itself the objective of investigating and documenting the way in which vulnerable populations coped with the lockdown period for controlling the Covid-19 crisis, in terms of the following three aspects: 1) The effects of reducing the public space, access to resources and available services and health care, limiting the ability of vulnerable populations to look after themselves, particularly in terms of health. 2) The way in which public policies for the Covid-19 epidemic were applied - or not - in practical situations facing vulnerable populations. 3) The ability of the stakeholders - including MSF - to offer a solution to health problems arising among these populations, both in terms of the epidemic, and more general health needs.

### **Inclusion criteria**

The study population concerned vulnerable individuals aged over 15 years, randomly and proportionally selected at each study site. The study sites were selected out of convenience, to fulfil the following criteria: sites still open and at which the MSF Covid Poverty project intervened at least once to provide medical and paramedical care, in the Paris and Seine Saint Denis administrative departments (main geographical zone of the MSF project), accepting populations suffering from economic and/or administrative instability, representing diverse forms of housing and accommodations, where the safety conditions at the time of the survey permitted, and after approval by the head of the association or housing facility.

## **REVISED HOME-COV - STUDY ON THE IMPLEMENTATION OF THE REVISED HOME-COV SCORE TO GUIDE THE CHOICE OF**

# **HOSPITALISATION OR OUTPATIENT MANAGEMENT OF PATIENTS WITH CONFIRMED OR PROBABLE SARS-COV-2 INFECTION ADMITTED TO AN EMERGENCY DEPARTMENT.**

Last update : 05/05/2021

Head :

Douillet Delphine

Responsible organization :

Angers University Hospital

## **Type of database**

Study databases

## **Study databases (details)**

Cohort study

## **Main objective**

The primary objective is to demonstrate the reliability and safety of outpatient management among patients highly suspected or confirmed as infected with COVID-19, attending an emergency department and with a revised HOME-CoV score less than 2 (negative rule).

The secondary objectives are as follows:

- i. Evaluate the rate of patients having required hospitalisation within 7 days following inclusion according to the revised positive or negative HOME-CoV rule.
- ii. Evaluate the rate of patients having required hospitalisation and initiation of oxygen therapy within 7 days following inclusion according to the revised positive or negative HOME-CoV rule.
- iii. Evaluate the rate of patients having required intubation within 7 days following inclusion according to the revised positive or negative HOME-CoV rule.
- iv. Evaluate the rate of all-cause deaths within 7 days following inclusion according to the revised positive or negative HOME-CoV rule.
- v. Evaluate the performance of the revised HOME-CoV score in predicting a negative outcome in the patient subgroup with SARS-CoV-2 infection confirmed by RT-PCR to rule out the risk of a negative outcome when assessed as low risk.
- vi. Compare the performance of the revised HOME-CoV score with that of other existing scores.

## **Inclusion criteria**

Adult patient (> 18 years),

- Attending one of the emergency departments taking part in the study due to COVID-19 infection confirmed by SARS-CoV-2 positive RT-PCR, or considered highly probable by the physician managing the patient,
- Not requiring management in a continuous care or intensive care unit, and subject to a decision to limit active treatment,
- Having given their formal consent to take part in the study,
- Registered with or a beneficiary of a social security scheme.

## **PIANO COVID-19 - EFFECT OF ORGANIZATIONAL MEASURES TO PREVENT AND CONTROL COVID-19 INFECTION IN NURSING**

# HOMES ON THE RISK OF DEATH OF RESIDENTS DURING AND AFTER THE EPIDEMIC PERIOD - PIANO COVID-19

Last update : 04/23/2021

Head :

ROLLAND Yves

Responsible organization :

Toulouse University Hospital

## Type of database

Study databases

## Study databases (details)

Cohort study

## Main objective

The main objective is to compare the occurrence of global death of residents during a 1-year period (from January 2020 to December 2020) in NH and LTCU with a high level of implementation of the recommendation/guidance to prevent and control COVID-19 NH/LTCU residents' infection and NH and LTCU with a low level of implementation of the recommendation/guidance to prevent and control COVID-19 NH/LTCU.

The secondary objectives are:

- To compare the rate of death related to confirmed or suspected COVID cases in NH/LTCU with a high level of implementation of the recommendation/guidance to prevent and control COVID-19 NH/LTCU residents' infection and NH/LTCU with a low level of implementation of the recommendation/guidance to prevent and control COVID-19 NH/LTCU.
- To compare the rate of death not related to COVID cases in NH/LTCU with a high level of implementation of the recommendation/guidance to prevent and control COVID-19 NH/LTCU residents' infection and NH/LTCU with a low level of implementation of the recommendation/guidance to prevent and control COVID-19 NH/LTCU.
- To analyze the incidence of serious health events (deaths, hospitalizations) and the occurrence of COVID in residents (vaccinated and unvaccinated), in NHs and LTCUs in France during a 12-month (2021) observation period.
- To analyze the occurrence of COVID in residents (vaccinated and unvaccinated), in NHs and LTCUs in France according to the rate of vaccination against COVID among the NH's/LTCU's staff during the same observational period.

From an economic perspective:

- To assess the economic impact of the implementation of prevention measures applied by nursing homes staff, from healthcare system and the NH perspectives, 6, and 12 months before and 6, 12 months to 24 months after the implementation of the preventive measures.
- To assess the economic impact of the vaccination among residents and NH's staff, from healthcare system and the NH perspectives, 6 and 12 months before and after the vaccination campaign. These data will also provide indirect economic information about the tolerance of the vaccination.
- To assess the efficiency of the high level implementation of the recommendation to prevent and control COVID-19 in comparison with the low level implementation of recommendation to prevent and control COVID-19, using a cost-effectiveness analysis at 12 and 24 months.
- To assess the efficiency of the vaccination, at 6 and 12 months, among residents and healthcare

professionals in comparison with no vaccination, using a cost-effectiveness analysis

## **Inclusion criteria**

NHs and LTCU volunteers to participate from different region of France (from low impacted to highly impacted region) will be welcomed.

### **NON-INCLUSION CRITERIA**

NHs or LTCUs that refuse to participate.

# **FACTORS INFLUENCING COMPLIANCE WITH OUTPATIENT EXERCISE TRAINING - FACTORS INFLUENCING COMPLIANCE WITH OUTPATIENT EXERCISE TRAINING FOR PATIENTS SUFFERING FROM COPD IN THE COVID-19 PANDEMIC CONTEXT**

Last update : 05/06/2021

Head :

Boudrahem Samir

Responsible organization :

AHREK

## **Type of database**

Study databases

## **Study databases (details)**

Not-repeated cross-sectional studies (except case control studies)

## **Main objective**

The primary objective of this research is therefore, initially, to shed light on the behaviour of patients suffering from obstructive pulmonary disease undergoing outpatient exercise training in the current context of the Covid-19 pandemic, based on 3 determining factors for behaviour, i.e.: motivation, capability and opportunity (COM-B, BCW model).

The feedback collected and analysed will then be compared with the data in the literature [4] [5] [6] [7] [8] [9] [10].

The secondary objectives will be to identify the factors facilitating or hindering compliance with exercise training which could be addressed by physiotherapists, and, lastly, to compare these findings with the possibilities and difficulties perceived by these professionals in supporting patients in this new context.

## **Inclusion criteria**

Inclusion criteria:

- Patients diagnosed with COPD
- Medical prescription for exercise training
- Males and females aged over 50 years, new to or already experienced in exercise training

Non-inclusion criteria:

- Patients without COPD
- No medical prescription for exercise training

Exclusion criterion:

- All categories of individuals under special protection with respect to French law (Articles L1121-8 -L1121-5

-L1121-6 -L1121-7 -L1121-9 of the French Public Health Code) are excluded

## **IBIS - POST-CRITICAL IMMUNOSUPPRESSION IN INTENSIVE CARE PATIENTS - IMMUNITY AFTER BRAIN INJURY STUDY**

Last update : 04/30/2021

Head :

ROQUILLY Antoine

Responsible organization :

Nantes University Hospital - Research Promotion

### **Type of database**

Others

### **Main objective**

The primary objective of this cohort with biocollections is to describe the epidemiology of medical complications arising during hospitalisation in an intensive care unit

### **Inclusion criteria**

All patients admitted to the surgical intensive care units at Nantes University Hospital, fulfilling the following

inclusion criteria:

1. Hospitalisation in intensive care > 48 hours
2. Aged over 15 years
3. Reason for hospitalisation including:
  - a. Severe injury with the need for mechanical ventilation > 24 hours
  - b. Acute brain injury with the need for mechanical ventilation > 24 hours
  - c. Septic shock

## **COVIPACT 2 - PSYCHOLOGICAL MANAGEMENT OF PATIENTS IN THE ONCOLOGY CONTEXT, PRESENTING POST-TRAUMATIC STRESS DISORDER IN THE CONTEXT OF THE COVID-19 EPIDEMIC**

Last update : 05/03/2021

Head :

NARAYANASSAMY Antony

Responsible organization :

François Baclesse Centre

### **Type of database**

Others

## Main objective

Evaluate the value of psychological management in patients with confirmed post-traumatic stress disorder (PTSD) related to the COVID-19 epidemic, in terms of the improvement in stress.

## Inclusion criteria

- Patient  $\geq$  18 years
- Patient treated or followed up for a solid tumour at the François Baclesse Cancer Centre
- Patient with a high post-traumatic stress disorder score (score  $\geq$  33 on the IES-R scale) related to the COVID-19 epidemic
- Patient state of health compatible with implementation of the programme: psychological management for 6 months
- Information leaflet signed by the patient
- Any associated geographical, social or psychopathological condition liable to compromise the patient's ability to take part in the study

# ALGOCOVID - SURVEY ON PAIN AND DISCOMFORT AMONG COVID-19 PATIENTS

Last update : 04/23/2021

Head :

LAFON Benoît

Responsible organization :

LDPD

## Type of database

Study databases

## Study databases (details)

## Main objective

This "Survey on pain and discomfort among Covid-19 patients" aims to develop our knowledge on acute pain in the course of the Covid-19 disease, together with pain and discomfort persisting after the acute phase of the disease

Secondary objectives:

- Determine the location and type of pain, together with pain intensity, number of different painful syndromes during and after the acute phase of the disease.
- Determine the specific prevalence of each painful syndrome identified, notably the prevalence of neuropathic pain.
- Determine the components causing residual discomfort.
- The endpoints, for each parameter measured, are the rate of positive answers in the corresponding existing sections (specific columns in the data collection table) or the rate of positive answers in the sections created during the analysis (calculation columns added, to meet objectives combining several existing sections).

## Inclusion criteria

Eligibility criteria:

- Male or female adult subject (18 years or over)
- AppliSamu record stating code VIN02, VIN03 or VIN06 between 01/03 and 31/05/2020

Inclusion criteria:

- Answering the telephone call (three attempts maximum)
- Patient's verbal agreement to a telephone interview
- Covid-19 disease confirmed by one of the following conditions:
  - AppliSamu code VIN06 (= confirmed Covid-19)
  - Code VIN02 or VIN03 (= suspected Covid-19) and patient confirming their positive diagnosis (by PCR, CT scan or appointment with an infectious diseases specialist)

## **- FORGOING CARE DURING THE LOCKDOWN PERIOD DUE TO THE COVID-19 EPIDEMIC**

Last update : 05/05/2021

Head :

Douillet Delphine, MITOVASC

Responsible organization :

Angers University Hospital

### **Type of database**

Study databases

### **Study databases (details)**

Not-repeated cross-sectional studies (except case control studies)

### **Main objective**

Compare the rate of patients forgoing care during the lockdown period in France, in emergency facilities at Angers and Le Mans hospitals, with that observed during a previous study in 2017.

### **Inclusion criteria**

All adult patients having attended the A&E department at Angers University Hospital and Le Mans Hospital, able and agreeing to complete the questionnaires directly or with the assistance of a translator.

## **PROF - SERMET-GAUDELUS ISABELLE**

Last update : 05/28/2021

Head :

Sermet-gaudelus isabelle, INSERM U 1151

Responsible organization :

APHP

### **Type of database**

Bases de données administratives pertinentes pour la santé

## Main objective

Etude de cohorte visant à identifier l'immunoprévalence et l'immunoprotection des enfants ayant un médecin référent à l'APHP (dans un centre recruteur) ou hospitalisés depuis moins de 5 jours dans des sites pédiatriques de l'APHP et un centre en Guyane et 1 de leurs parents.

### Etude longitudinale

- sur la sous-population des enfants et leurs parents positifs en PCR, quel que soit le prélèvement (cohorte principale)

- 3 visites à domicile ou à l'hôpital à court terme (J 7, J15, J45 post début des symptômes ayant motivé l'hospitalisation ou du prélèvement si enfant asymptomatique) visant à évaluer la cinétique de la réponse immunitaire et de la clairance virale

- 2 visites à long terme (6 mois et 1 an) visant à évaluer la cinétique du taux des Ac et l'évaluation de la mémoire immunitaire.

- Dépistage d'éventuelles réinfections par des prélèvements de salive si le patient présente des symptômes compatibles avec une nouvelle infection COVID

- en cas de réinfection authentifiée par PCR salive + SARS-CoV2:

- prélèvement sanguin (caractérisation de la réponse immunitaire humorale et cellulaire chez des patients pauci-symptomatiques) ;

- prélèvements de selles, et nasopharynx si accord des parents (infection des différents sites, viabilité du virus, mutations de SARS CoV2) ;

- Sur la sous population des enfants séropositifs ou fortement suspects d'infections COVID repérés lors de la 1ere vague : prélèvement à la rentrée 2020, soit environ 6 mois après l'infection (cohorte associée)

Cohorte famille visant à évaluer la transmission du virus de l'enfant aux autres membres de la famille : 5 visites à domicile post-dépistage positif

## Inclusion criteria

Cohorte principale :

### 1) Enfants

- tout enfant de plus de 7 jours et moins de 17 ans en consultation ou hospitalisé depuis au plus 4 jours à l'AP-HP ou au CH Cayenne;

- ou tout enfant de plus de 7 jours et moins de 17 ans, considéré comme infecté par SARS-CoV2 du fait d'un test positif en PCR ou en test antigénique , quel que soit le site -ces tests peuvent être réalisés à l'APHP, ou au domicile, l'enfant ayant un médecin référent à l'AP-HP (dans un centre recruteur); quels que soient les symptômes ;

- accord du parent présent pour le prélèvement sanguin, salivaire et rectal

- accord optionnel pour le prélèvement nasopharyngé

- accord optionnel pour les prélèvements au domicile et au CIC ou à l'hôpital de référence si patient positif en qPCR

- affiliation à un régime de sécurité sociale.

## 2) adultes

- un des parents de l'enfant inclus dans la cohorte principale de l'étude PED-COVID

- Donnant son accord pour prélèvement sanguin et salive

- Accord optionnel pour prélèvement nasopharynx

- accord optionnel pour les prélèvements au domicile et au CIC ou à l'hôpital de référence si sujet positif en qPCR

- affiliation à un régime de sécurité sociale.

## Cohorte associée :

- tout enfant de plus de 7 jours et moins de 17 ans; séropositif par la technique LIPS/Pasteur repéré par la 1ere étude lors de la 1ere vague, quel que soit le délai entre le diagnostic et l'inclusion dans PED-COVID

OU

- tout enfant de plus de 7 jours et moins de 17 ans; ayant présenté une atteinte clinique inflammatoire potentiellement reliée à SARS-CoV2, sur des arguments épidémiologiques, cliniques, infectieux ou sérologiques quel que soit le délai entre le diagnostic et l'inclusion dans PED-COVID

- affiliation à un régime de sécurité sociale.

- Cohorte famille

### 1) Cas index

- tout enfant de moins de 18 ans

- scolarisé

- considéré comme infecté par SARS-CoV2 du fait d'un test positif en PCR ou en test antigénique quel que soit le site accord du parent présent pour le prélèvement sanguin et salivaire

- accord optionnel pour le prélèvement nasopharyngéaffiliation à un régime de sécurité sociale

### 2) Autres membres vivants sous le même toit

- tout enfant, quel que soit son âge ou adulte vivant sous le même toit qu'un enfant infecté inclus dans PED-COVID-cohorte famille

· affiliation à un régime de sécurité sociale

## **RAPID'COVID - ETUDE DES PERFORMANCES ANALYTIQUES COMPARÉES D'UN NOUVEAU KIT DE DÉTECTION MOLÉCULAIRE DU COVID-19 RAPIDES (LOOP-XPLORE) EN AMBULATOIRE (MODE NON-EXPERT, BAS DÉBIT - POINT OF CARE) ET EN LABORATOIRE DE VIROLOGIE (MODE EXPERT, HAUT DÉBIT, DIAGNOSTIC MÉDICAL).**

Last update : 10/01/2021

Head :

LE GOUIL Meriadeg, Laboratoire de virologie

Responsible organization :

CHU de Caen

### **Type of database**

Autres

### **Main objective**

Evaluer la concordance entre l'outil de détection moléculaire rapide du virus SARS-CoV-2 (technique Loop-Xplore) dans les prélèvements nasopharyngés et salivaires en ambulatoire et la technique PCR de référence réalisée au laboratoire de virologie du CHU de Caen.

### **Inclusion criteria**

- Patient majeur adressé pour la réalisation d'un test nasopharyngé de diagnostic d'infection à SARS-CoV-2 (COVID19)
- Patient ayant été informé de l'étude et ayant accepté de participer
- Patient francophone et affilié au régime de la sécurité sociale

## **COVIMMUNE 2 - STUDY OF THE INCIDENCE OF SARS-COV-2 INFECTION IN THE ALPES-MARITIMES ADMINISTRATIVE DEPARTMENT BASED ON THE ANALYSIS OF SPECIFIC HUMORAL AND CELLULAR RESPONSE WHILE EASING LOCKDOWN RESTRICTIONS**

Last update : 10/01/2021

Head :

SEITZ-POLSKI Barbara, laboratoire d'Immunologie hôpital Archet 1

Responsible organization :

Nice University Hospital

### **Type of database**

Study databases

## **Study databases (details)**

Cohort study

### **Main objective**

Determine the incidence of SARS-CoV-2 infection, over an 18-month period after the end of the first lockdown in a group of subjects whose professions involve contact with the general public.

Determine the risk of re-infection after initial infection with SARS-CoV-2 confirmed by a positive serology test.

### **Inclusion criteria**

Any healthy adult volunteers, exposed to the general public from 11 May 2020, informed of the study via partner institutions (06 Administrative Department Council), registered with a social security scheme.

## **EVANESCO - COHORT EVENT MONITORING OF COVID-19 VACCINE SAFETY IN FRANCE USING PATIENT-REPORTED OUTCOMES**

Last update : 03/07/2023

Head :

Thurin Nicolas, Bordeaux PharmacoEpi (BPE) Research Platform - Inserm CIC1401

Responsible organization :

University of Bordeaux, Bordeaux PharmacoEpi (BPE) Research Platform Inserm CIC1401

### **Type of database**

Study databases

## **Study databases (details)**

Cohort study

### **Main objective**

To generate incidence rates of patient-reported Adverse Drug Reaction (ADR) of brand specific COVID-19 vaccination in France, in near real time.

### **Inclusion criteria**

- To describe ADR incidence rates according to brand of vaccine and to specific populations such as, pregnant women, patients with severe co-morbidities (e.g., frail, vaccinees with auto-immune diseases), elderly, children, patients having recently received other vaccines;
- To detect potential novel safety signals;
- To identify possible risk factors for ADR.

## **AL43751 - ACCÈS PRÉCOCE RONAPREVE EN PROPHYLAXIE PRÉ-EXPOSITION DES FORMES SÉVÈRES DE COVID-19**

Last update : 03/07/2023

Head :

ROCHE SAS , ROCHE SAS

Responsible organization :  
ROCHE SAS

## Type of database

Autres

## Main objective

Etudier l'efficacité et la tolérance de Ronapreve dans l'indication concernée par l'accès précoce

## Inclusion criteria

En prophylaxie pré-exposition de l'infection à SARS-CoV-2 chez les patients adultes et les enfants âgés de 12 ans et plus, faiblement répondeurs à la vaccination après un schéma vaccinal complet conformément aux recommandations en vigueur ET appartenant à l'un des sous-groupes à très haut risque de forme sévère de COVID-19 tels que définis par l'ANRS-Maladies Infectieuses Emergentes :

- receveurs de greffes d'organes solides,
- receveurs d'une greffe allogénique de cellules souches hématopoïétiques,
- patients souffrant d'une hémopathie lymphoïde (leucémies lymphomes chroniques traitées ou non, lymphomes non hodgkiniens et myélomes sous traitement, y compris les patients receveurs de thérapie cellulaire génique de type CAR-T cell (chimeric antigen receptor T cell) ou d'anticorps thérapeutiques bi-phénotypiques),
- patients recevant un traitement par anticorps anti-CD20 ou inhibiteurs de BTK (Bruton tyrosine kinase) ou azathioprine, cyclophosphamide et mycophénolate mofétil,
- sujets porteurs d'un déficit immunitaire primitif».