

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

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

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General	
Identification	
Detailed name	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
Sign or acronym	COVIMMUNE 2
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	2020-A01677-32
General Aspects	
Medical area	Biology Immunology Infectious diseases
Study in connection with Covid-19	Yes
Pathology (details)	Humoral and cellular immune response to SARS-CoV-2
Health determinants	Geography Lifestyle and behavior Occupation Pollution Social and psychosocial factors
Keywords	easing of lockdown restrictions, interferon, SARS-CoV-2 COVID-19 Serology, immunovirology, incidence
Scientific investigator(s) (Contact)	
Name of the director	SEITZ-POLSKI

Surname	Barbara
Address	Hôpital de l'Archet 1 BP 3079 151 ROUTE ST ANTOINE DE GINESTIERE 06202 NICE CEDEX 3
Phone	0492035990
Email	seitz-polski.b@chu-nice.fr
Unit	laboratoire d'Immunologie hôpital Archet 1
Organization	Nice University Hospital
Collaborations	
Participation in projects, networks and consortia	Yes
Details	Department of Public Health - Nice University Hospital
Others	Alpes-Maritimes Administrative Departmental Council
Funding	
Funding status	Public
Details	Alpes-Maritimes Administrative Departmental Council, Regional Council, Nice University Hospital Research Unit
Governance of the database	
Sponsor(s) or organisation(s) responsible	Nice University Hospital
Organisation status	Public
Presence of scientific or steering committees	Yes
Labelling and database evaluation	Nice University Hospital
Additional contact	
Name of the contact	ALLOUCHE
Surname	Jonathan

Address	Hôpital de l'Archet 1 BP 3079 151 ROUTE ST ANTOINE DE GINESTIERE 06202 NICE CEDEX 3
Email	allouche.j@chu-nice.fr
Organization	Department of Public Health, Nice University Hospital

Name of the contact	Zorzi
Surname	Kévin
Address	Hôpital Pasteur 1 CHU de Nice
Phone	0492037917
Email	zorzi.k@chu-nice.fr
Organization	Nice University Hospital Clinical Research

Name of the contact	PRADIER
Surname	Christian
Address	Hôpital de l'Archet 1 BP 3079 151 ROUTE ST ANTOINE DE GINESTIERE 06202 NICE CEDEX 3
Phone	0492035630
Email	pradier.c@chu-nice.fr
Organization	Department of Public Health, Nice University Hospital

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services A population file

Database recruitment is carried out as part of an interventional	No
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study

Additional information regarding sample selection.

Prospective recruitment of healthy adult volunteers for COVID-19 exposed daily to SARS-CoV-2 from 11 May 2020 (not under lockdown restrictions), in a hospital setting (Nice University Hospital) and non-hospital setting (administrative department council officers, municipal officers).

Database objective

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.

Population type

Age

Adolescence (13 to 18 years)
Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered

General population

Pathology

Gender

Male
Woman

Geography area

Departmental

French regions covered by the database

Provence - Alpes - Côte d'Azur

Detail of the geography area

Alpes-Maritimes

Data collection

Dates

Date of first collection (YYYY or

2020

MM/YYYY)

Date of last collection (YYYY or MM/YYYY)	2022
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Size of the database

Size of the database (number of individuals)	[500-1000[individuals
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Details of the number of individuals	Approximately 560
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Declarative data Paraclinical data Biological data Administrative data
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Clinical data (detail)	Medical registration
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Details of collected clinical data	Clinical examination at inclusion
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Declarative data (detail)	Paper self-questionnaire Face to face interview
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Details of collected declarative data	Self-administered questionnaire and in-person interview at inclusion
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Paraclinical data (detail)	Anthropometric data
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Biological data (detail)	Blood sample: Anti-SARS-CoV-2 IgA and IgG serology, QuantiFERON Monitor
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Administrative data (detail)	Gender, age, date and place of birth, marital status, number of children, most recent qualification
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Presence of a biobank	Yes
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Contents of biobank	Serum Plasma Others
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Details of biobank content	Other: Stimulated cell supernatant
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Health parameters studied	Health event/morbidity Quality of life/health perception
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Quality of life/perceived health (detail)

Self-assessment of general state of health, self-assessment of stress level

Procedures

Data collection method

Self-administered paper questionnaire, in-person interview, clinical examination and blood sample

Quality procedure(s) used

Verification of electronic data entry. Database data management with consistency tests. Patients are informed of the use of their data.

Participant monitoring

Yes

Monitoring procedures

Monitoring by contact with the participant (mail, e-mail, telephone etc.)
Monitoring by convocation of the participant

Details on monitoring of participants

Follow-up duration 5 years after inclusion. Possibility of correspondence via a secure messaging platform. Invitation by email and electronic platform for the visits at 6 months and 12 months after inclusion. Annual self-administered questionnaire sent out via a secure messaging platform 24, 36, 48 and 60 months after inclusion.

Links to administrative sources

No

Promotion and access

Promotion

Link to the document

<https://clinicaltrials.gov/ct2/show/NCT04429594>

Description

Details of the study on Clinical Trial

Link to the document

<https://pubmed.ncbi.nlm.nih.gov/33585507/>

Description

Severe COVID-19 and evasion of interferon response

Link to the document

<https://pubmed.ncbi.nlm.nih.gov/33585509/>

Description

Humoral and cellular response to SARS-CoV-2 infection in exposed nursing staff at Nice University Hospital

Access