

CARBO - Descriptive and prognostic study of arbovirus infections in France, based on a hospital cohort of children and adults with suspected arbovirose

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General

Identification

Detailed name Descriptive and prognostic study of arbovirus infections in France, based on a hospital cohort of children and adults with suspected arbovirose

Sign or acronym CARBO

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation 2010-A00282-37 (Sud Ouest and Outre Mer III ethics committee) (CPP), 30 June 2010- No. 2, 31 July 2013, No. 3 on 28/05/2014, No. 4 on 30/07/2014, No. 5 on 24/09/2014, No. 6 on 17/01/2016, No. 7 on 30/03/2016, No. 8 on 31/08/2016, No. 9 on 29/03/2017, No. 10 on 31/07/2017, ANSM - 11 June 2010, No. 2 on 08 August 2013, No. 3 on 27/05/2014, Nos. 4 and 5 on 26/09/2014, Nos. 6 and 7 on 04/05/2016, No. 8 on 23/03/2017, No. 9 on 23/03/2017, No. 10 on 22/05/2017

General Aspects

Medical area Immunology
Infectious diseases

Pathology (details) Dengue, Chikungunya, Zika and other arboviruses

Health determinants Genetic

Keywords Dengue, Chikungunya, French Guiana, virus, infection, management, Zika, West Indies, France, Arboviruses

Scientific investigator(s) (Contact)

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Unit

Equipe d'accueil 4537, Université des Antilles et de la Guyane

Organization

CHU de Martinique

Collaborations

Participation in projects, networks and consortia

Yes

Details

Reacting

Others

Institut Pasteur

Funding

Funding status

Public

Details

DGOS: PHRC/ SERI

Governance of the database

Sponsor(s) or organisation(s) responsible

CHU de Martinique

Organisation status

Public

Presence of scientific or steering committees

Yes

Additional contact

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

Database recruitment is carried out as part of an interventional study

Yes

Details

Performed at individual level

Additional information regarding sample selection.

The study is offered to all patients who fit into the inclusion criteria, calling upon one of the hospital departments involved in the research.

Database objective

Main objective

To identify demographic, clinical, biological, virologic, immunologic and genetic factors associated with or predictive of severe complications of arbovirus infections (shock, internal bleeding, organ failure, death) in a cohort of children and adults with confirmed arbovirus infections, in France.

Inclusion criteria

- Adult, child or newborn with a weight > 2.5 kg the days of enrollment.
- Consulting a participating hospital center (emergency room, full hospitalization, day hospitalization, or outpatient visit).
- Arbovirosis suspected or confirmed biologically: A suspected case of arbovirus infection is defined by:
 - The combination of clinical and biological signs observed on the day of enrollment or during the previous 7 days: fever (reported by the patient or family, or documented) and two or more of the following signs: headache, rash, myalgia, arthralgia, abdominal pain, hemorrhage, thrombocytopenia, or
 - Children under 6 years: the report (by family or documented) of a fever on the day of enrollment or within 7 previous days, possibly accompanied by a of pain greater than or equal to 4/10 on hetero assessment scale age age-appropriate
- At a patient with a notion of stay in 2 weeks preceding in a zone of arbovirus circulation (only for the imported cases)

A case of arbovirus infection confirmed biologically is defined by:

- RT-PCR arbovirus positive in plasma or urine (Zika virus infection), or by detection of the NS1 antigen (dengue), or an appearance or an significant increase (multiplication of the title by four) of the G immunoglobulin directed against arbovirus in question on an early taken serum (during the first week following the start of symptoms) and another taken at least 10 days later..
- Symptom onset within the seven days before the enrollment visit or within 21 days for severe forms of the disease. Possibility of follow-up throughout

study period.
- Acceptance to participate in the study and in follow-up; informed consent of the patient (adult and minor in age to express his desire) or a legal representative (for minors, and patients unable to sign the consent form).

Population type

Age
Newborns (birth to 28 days)
Infant (28 days to 2 years)
Early childhood (2 to 5 years)
Childhood (6 to 13 years)
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 Sick population

Pathology B99-B99 - Other infectious diseases

Gender Male
Woman

Geography area Regional

French regions covered by the database
Île-de-France
Guadeloupe
Guyane
Martinique
La Réunion

Detail of the geography area West Indies, French Guiana, metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2010

Date of last collection (YYYY or MM/YYYY) 2018

Size of the database

Size of the database (number of individuals) [1000-10 000[individuals

Details of the number of 1377

Data

| Database activity | Current data collection |
|---------------------------------------|--|
| Type of data collected | Clinical data Declarative data Paraclinical data Biological data |
| Clinical data (detail) | Direct physical measures Medical registration |
| Details of collected clinical data | Cardinal and noncardinal signs and symptoms of an arbovirus. Photographs of dermatological and musculoskeletal manifestations (if available as part of the care). Assessment of pain intensity on a visual analogue scale, Evaluation of the neuropathic components of pain using the DN4 questionnaire, Evaluation of the general condition of the patient as well as the articular involvement by MDHAQ and RAPID3 scores. Assessment of quality of sleep and quality of life by validated specific scores |
| Declarative data (detail) | Face to face interview Phone interview |
| Details of collected declarative data | Demographics |
| Paraclinical data (detail) | NFS, platelets, biochemistry, leukocyte sorting and labelling by flow cytometry, radiology (if available as part of the care). |
| Biological data (detail) | The plasma viraemia measured by specific qRT-PCR-arbovirus, the titre of specific antibodies against an arbovirus, in particular IgM, IgG and IgA. |
| Presence of a biobank | Yes |
| Contents of biobank | Whole blood Serum Plasma Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?) Buccal cells DNA DNAc/RNA Others |
| Details of biobank content | From the collection of biological samples (scientific collaboration): Analyse virological markers (tropism, |

phylogeny) in venous and capillary blood, urine, stools, tears, pharyngeal secretions, saliva, sperm, vaginal secretions, milk for lactating women and joint fluid (if indicated as part of the care for the latter) according to the sampling schedule proposed by this sub-study. Determine the kinetics of the innate immune response from the evaluation of dendritic cells, study the expression of proinflammatory cytokines and the gene expression profile according to the proposed sampling schedule.

Health parameters studied

Health event/morbidity
Health event/mortality
Health care consumption and services
Quality of life/health perception

Quality of life/perceived health (detail)

EQ-5D questionnaire

Procedures

Data collection method

An electronic data collection is provided for each patient. There is nevertheless a paper medium allowing, if necessary, delayed filling in of the electronic observation log.

Quality procedure(s) used

The Methodology and Data Management centre is the CIC Antilles-Guyane (CIC1424). Data entry is carried out on the Clinsight® platform of the CIC Antilles-Guyane.

Participant monitoring

Yes

Monitoring procedures

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

Details on monitoring of participants

Follow-up from D1 to D7, D3, D5-D7, D8-D10, D21, W6, W12, M6, M12, M18, M24, M36

Links to administrative sources

No

Promotion and access

Promotion

Link to the document

[Cabie? et al. - 2015 - Chikungunya Virus Infections.pdf](#)

Link to the document

[Zika virus detection in urine.pdf](#)

Link to the document

[Zika virus detection in cerebrospinal fluid.pdf](#)

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|----------------------|---|
| Link to the document | Zika emergence in the French Territories of America.pdf |
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Access

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|---|-----|
| Presence of document that lists variables and coding procedures | Yes |
|---|-----|

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|---|---------------------------------|
| Terms of data access (charter for data provision, format of data, availability delay) | Contact the scientist in charge |
|---|---------------------------------|

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|---------------------------|---------------------------------|
| Access to aggregated data | Access on specific project only |
|---------------------------|---------------------------------|

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| Access to individual data | Access on specific project only |
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