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

individuals

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/RNAm 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

Link to the document	Zika emergence in the French Territories of America.pdf
Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only