

CHIMERE - Mother-to-Child Chikungunya virus infection: an ambispective cohort study

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General

Identification

Detailed name Mother-to-Child Chikungunya virus infection: an ambispective cohort study

Sign or acronym CHIMERE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL 1836406, CPP Tours 2006/2007

General Aspects

Medical area Infectious diseases

Keywords Chikungunya virus; pregnancy; obstetrics; perinatal medicine; mother; neonate; mother-to-child transmission; pediatrics; children; encephalitis; encephalopathy; neurodevelopmental outcome; sequelae; cohort studies

Scientific investigator(s) (Contact)

Name of the director Gérardin

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| Organization | 2224Inserm CIC-P 1402 Centre d'Investigation Clinique Plurithématique du CHU de Poitiers. http://cic0802.labo.univ-poitiers.fr |

Collaborations

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|--|-----|
| Participation in projects, networks and consortia | Yes |
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|---------|--|
| Details | Reacting network for the Chikungunya in French West Indies and Guyana |
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Funding

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|----------------|--------|
| Funding status | Public |
|----------------|--------|

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|---------|-----------------|
| Details | PHRC grant 2006 |
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Governance of the database

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|--|-------------------|
| Sponsor(s) or organisation(s) responsible | CHU de la Réunion |
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Organisation status Public

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 No

Additional information regarding sample selection. Ambispective: prospective enrolment of consecutive mother-infant pairs from April, 2006 to November, 2006; retrospective enrollment of 33 additional mother-infant pairs whose child had been infected between June 2005 to April 2006.

Database objective

Main objective 1- Primary objective: to assess the prevalence and the neurodevelopmental outcomes of maternal-fetal chikungunya infection ; 2-Secondary objectives: to decipher the mechanisms and risk factors of mother-to-child chikungunya virus transmission; to describe the chikungunya virus in the pregnant woman and in the neonate; to propose a guideline for diagnosis and treatment of infections over pregnancy, childbirth and neonatal periods; to valid the virological diagnosis in the neonate using cord blood RT-PCRs; to study viral strains; to describe in children exposed in utero to maternal infection the kinetics of seroreversion of maternal transplacental IgG antibodies.

Inclusion criteria Maternal study: pregnant women with life insurance cover; Child study: children born from women enrolled in t the maternal cohort. Inclusion whatever the pregnancy story and the exposure the first two months, then only the exposed women reporting a chikungunya attack the next six following months.

Population type

Age Newborns (birth to 28 days)

Infant (28 days to 2 years)

Population covered General population

Gender Woman

Geography area Departmental

French regions covered by the database La Réunion

Detail of the geography area Cohort study conducted in four public maternities: Saint Denis, Saint Louis, Saint Paul, Saint Pierre; one semi-public semi-private maternity: Saint Benoît; one private maternity: Sainte Clotilde

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 06/2005

Date of last collection (YYYY or MM/YYYY) 10/2008

Size of the database

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

Details of the number of individuals 1433

Data

Database activity Data collection completed

Type of data collected
Clinical data
Declarative data
Paraclinical data
Biological data
Administrative data

Clinical data (detail) Direct physical measures
Medical registration

Details of collected clinical data Mothers: inclusions, clinical examinations and anthropometric measures during pregnancy and/or at childbirth. Children: inclusions and clinical examinations and anthropometric measures at birth, 9-12 months (CLAMS and babyvision), 18-24 months (revised Brunet-Lezine DQ)

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| Declarative data (detail) | Face to face interview |
| Details of collected declarative data | Mothers: inclusions, clinical examinations and anthropometric measures during pregnancy and/or at childbirth. Children: inclusions and clinical examinations and anthropometric measures at birth, 9-12 months (CLAMS and babyvision), 18-24 months (revised Brunet-Lezine DQ) |
| Paraclinical data (detail) | Mothers: virological and serological examinations during pregnancy and/or at childbirth. Children: virological and serological examinations at birth, then serological examinations exclusively at 3 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months. |
| Biological data (detail) | Mothers: blood numeration and formula at childbirth; children: blood numeration and formula at birth |
| Administrative data (detail) | Hospital stays |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity Health event/mortality |
| Procedures | |
| Data collection method | Data collected by hospital-based gynecologists-obstetricians, midwives, neonatologists-pediatricians, psychometrists, neuropsychologists in CAMSP centers at the different time-points of follow-up (see above). |
| Participant monitoring | Yes |
| Details on monitoring of participants | Children: clinical examinations and anthropometric measures at birth by neonatologists-pediatricians at 9-12 months (CLAMS and babyvision by psychometrists), at 18-24 months (revised Brunet-Lezine DQ by blind neuropsychologist of the infectious status);Serological examinations at 3 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, 24 months. |
| Links to administrative sources | No |

Promotion and access

Promotion

Link to the document <http://www.sciencedirect.com/science/article/pii/S1201971208001586>

Link to the document <http://wwwnc.cdc.gov/eid/article/16/3/pdfs/09-1403.pdf>

Link to the document <http://tinyurl.com/HAL-CHIMERE>

Description List of publications in HAL

Link to the document <http://tinyurl.com/Pubmed-CHIMERE>

Description List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay) modalities of access to the database in progress.

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only