

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)	
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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	
Participation in projects, networks and consortia	Yes
Details	Reacting network for the Chikungunya in French West Indies and Guyana
Funding	
Funding status	Public
Details	PHRC grant 2006
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHU de la Réunion

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 enrollement 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-Secundary 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)

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