

CEREVANCE - National Prospective Cohort Follow-Up for Children with Severe Autoimmune Cytopenia

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Last update : 08/12/2014 | Version : 1 | ID : 60196

General

Identification

Detailed name National Prospective Cohort Follow-Up for Children with Severe Autoimmune Cytopenia

Sign or acronym CEREVANCE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation Accord CNIL: 17/11/2004

General Aspects

Medical area Cardiology
Immunology
Rare diseases

Health determinants Genetic

Others (details) Autoimmune cytopenia, autoimmune haemolytic anaemia, Evans syndrome, chronic immune thrombocytopenic purpura

Keywords Clinical progression, prognostic factors, autoimmune haemolytic anaemia, Evans syndrome, chronic immune thrombocytopenic purpura, research network, biobank, physiopathological mechanisms of these diseases, child

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
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Details	Institut des Maladies Rares (2004), Ministère de la santé (PHRC 2005), Centre de Référence Maladies Rares (2007)
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Governance of the database

Sponsor(s) or organisation(s) responsible	CHU Bordeaux
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Organisation status	Public
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Additional contact

Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is carried	No
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out as part of an interventional study

Additional information regarding sample selection.

Prospective Inclusion cut-off date: 01/06/2011

Database objective

Main objective

General objective: To prospectively study clinical and paraclinical evolution as well as prognostic factors for autoimmune haemolytic anaemia, Evans syndrome and chronic immune thrombocytopenic purpura among children in France - To generate support for a basic and therapeutic research network for these diseases Secondary objectives - To develop a biobank to study the physiopathological mechanisms of these diseases - To generate support for a national network for epidemiological, clinical, biological and therapeutic research for these diseases

Inclusion criteria

Under 18 years of age and affiliated with a social security scheme - Living in mainland France Patients with AIHA, chronic ITP and/or ES, regardless of underlying factors Free informed written and signed consent by parental authority holders as well as the child or adolescent if they are of age Exclusion criteria: constitutional haemolytic anaemia and constitutional platelet disease

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)

Population covered

Sick population

Gender

Male
Woman

Geography area

National

Detail of the geography area

Multicentric cohort throughout France (30 centres)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

06/2008

Date of last collection (YYYY or MM/YYYY)	06/2011
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	265
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data Biological data
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Clinical data (detail)	Direct physical measures Medical registration
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Declarative data (detail)	Paper self-questionnaire
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Biological data (detail)	FBC, reticulocytes, blood group, rhesus, haemolysis markers (haptoglobin, LDH, total and unconjugated bilirubin), renal function, liver function test, Coombs test, MAIPA, immunoglobulin quantitation, lymphocyte phenotyping, autoantibody markers (FAN, anti-DNA, anti-phospholipid, thyroid ...), other examinations according to clinical context
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Presence of a biobank	Yes
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Contents of biobank	Whole blood Serum Plasma DNA
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Details of biobank content	Serum bank, Plasma bank, DNA bank
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Health parameters studied	Health event/morbidity Health event/mortality
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Procedures

Data collection method	Clinical examinations: manual input with double data entry Biological analysis: manual input with double data entry
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Participant monitoring	Yes
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Details on monitoring of participants	Minimum follow-up every 6 months for 3 years, then annual
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Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term
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Access

Terms of data access (charter for data provision, format of data, availability delay)	To be decided if data may be used by academic teams To be decided if data may be used by industrial teams
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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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