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

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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
Details	Institut des Maladies Rares (2004), Ministère de la santé (PHRC 2005), Centre de Référence Maladies Rares (2007)

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU Bordeaux
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	No

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
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	265
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
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
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma DNA
Details of biobank content	Serum bank, Plasma bank, DNA bank
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Clinical examinations: manual input with double data entry Biological analysis: manual input with double data entry
Participant monitoring	Yes

Details on monitoring of participants	Minimum follow-up every 6 months for 3 years, then annual
Links to administrative sources	No

Promotion and access

Promotion

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

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