

CEMARA - Inflammatory Diseases in Paediatric Rheumatology

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Last update : 08/14/2014 | Version : 2 | ID : 60138

General

Identification

Detailed name Inflammatory Diseases in Paediatric Rheumatology

Sign or acronym CEMARA

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL 1187326 (23/05/2007)

General Aspects

Medical area Rheumatology

Health determinants Genetic

Keywords adverse events, life-threatening, sequelae, embryonic/foetal impairment, neoplasia, Health episodes, death, hospitalisation

Scientific investigator(s) (Contact)

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Unit UNITE D'IMMUNO-HEMATOLOGIE PEDIATRIQUE

Organization UIH) ET INSERM U768 HOPITAL NECKER-ENFANTS MALADES

Collaborations

Participation in projects, networks and consortia Yes

Funding

Funding status Public

Details CENTRE DE REFERENCE MALADIES RARES «
ARTHRITES JUVENILES »

Governance of the database

Sponsor(s) or organisation(s) responsible INSERM - Institut National de Santé et Recherche Médicale

Organisation status Public

Sponsor(s) or organisation(s) responsible APHP

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. Inclusion method: Prospective Inclusion cut-off date not determined

Database objective

Main objective General objective: To evaluate the risk of the occurrence of serious adverse events under or after exposure to prescribed biotherapy for rheumatoid arthritis. The selected population consists of a growing proportion of patients exposed to early introductory biotherapy from childhood (TNF-Alpha antagonists, IL-1, IL-6, anti-CD20, CTLA-4Ig etc.), sometimes in combination with immunosuppressants Secondary objectives: 1/ To simultaneously assess the risk of the occurrence of serious adverse events (SAE) in the absence of biotherapy for the entire paediatric rheumatology cohort. 2/ To assess the risk of SAEs in the

presence or absence of biotherapy for main sub-cohorts: juvenile idiopathic arthritis, paediatric autoimmune diseases, systemic vasculitis and childhood collagen diseases including lupus. 3/ To describe progressive characteristics and treatment of these patients in more detail. 4/ To further basic, clinical and epidemiological studies by creating a biobank and connections with other cohorts and registries 5/ To promote the assessment of medical practices and the application of national protocol recommendations for diagnosis and care.

Inclusion criteria	Patients included in the CEMARA database must have a diagnosis relevant to the label "juvenile arthritis" in the rare disease reference centre = inflammatory paediatric rheumatology diseases identified in the CEMARA thesaurus (and Orphanet thesaurus) belonging to one of the following 4 categories: juvenile idiopathic arthritis, other juvenile arthritis, paediatric autoinflammatory diseases, systemic diseases and paediatric vasculitis
Population type	
Age	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
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	05/2007
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1068
Data	

Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures Medical registration
Presence of a biobank	Yes
Contents of biobank	Serum Plasma DNA DNAC/RNAm
Details of biobank content	Serum bank, plasma bank, DNA bank, RNA (TEMPUS TUBES OR EQUIVALENT)
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Interview: Direct input Clinical examinations: Direct input
Participant monitoring	Yes
Details on monitoring of participants	(Indefinite duration)
Links to administrative sources	Yes
Linked administrative sources (detail)	CépiDc
Promotion and access	
Promotion	
Access	
Dedicated website	https://cemara.org
Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams. Contractual access. Data may not be used by industrial teams
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only