PAEDIATRIC IBD (MICI PEDIATRIQUE) - Cohort of Children with IBD (Inflammatory Bowel Disease)

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Last update : 06/27/2014 | Version : 2 | ID : 60126

General

Identification

Detailed name	Cohort of Children with IBD (Inflammatory Bowel Disease)
Sign or acronym	PAEDIATRIC IBD (MICI PEDIATRIQUE)
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP no.: 2007/32 and AFSSAPS no.: 2007-A00468-45

General Aspects

Medical area	Immunology Radiology and medical imaging Rare diseases
Health determinants	Genetic
Keywords	inflammatory diease, hospitalisation, treatment, complications, death

Scientific investigator(s) (Contact)

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Name of the director	Gower-Rousseau

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Collaborations

Others	Other related cohorts: some general population paediatric cohorts, particularly in Scandinavia and Scotland.

Funding

Funding status	Mixed
Details	Clinical research hospital programme. Association François-Aupetit (patients' association).

Governance of the database

Sponsor(s) or organisation(s) responsible	CENTRE D'INVESTIGATION CLINIQUE DU CHRU DE LILLE
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.	Retrospective. Other bodies active in creating this cohort: CHU, CHG, Independent physicians. Closing date for inclusion: 01/12/2004.

Database objective

Main objective	To study the correlations between phenotypic peculiarities in patients (onset of IBD, disease progression, treatment response), ASCA and ANCA

serological markers and allelic status of NOD2/CARD15 gene.

Secondary objectives:
- to analyse therapeutic management and surgical predictors for each UC and CD group;
- to investigate the development of paediatric forms in adulthood in terms of growth (Z score) and socio-professional level (level of education, age and category of last diploma, current profession);
- to establish a database to evaluate the impact of other genetic polymorphisms in order to investigate possible epistasis of these polymorphisms with CARD15/NOD2.

Inclusion criteria	The cohort consists of children with certain or probable Crohn's Disease (CD) or certain or probable ulcerative colitis (UC) identified in the EPIMAD registry between 1988 and 2002. Children: under 17 years old at the time of diagnosis

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	Départements: Nord, Pas-de-Calais, Somme, and Seine-Maritime (5.8 million inhabitants)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	01/1988
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database

Size of the database (number of	[500-1000[individuals

individuals)

Details of the number of individuals	698

Data

Database activity	Data collection completed
Type of data collected	Declarative data Paraclinical data Biological data
Declarative data (detail)	Face to face interview
Details of collected declarative data	Information sheet at baseline and throughout follow-up (every year) completed by the specialist physician/researching physician. Information collected: -clinical, -radiological, -endoscopic, -weight, -height, -treatment.
Paraclinical data (detail)	Imaging: x-ray of small intestine, colon, ultrasound, enteric MRI, etc. Digestive endoscopy and histology.
Biological data (detail)	- 2 tubes of 7 ml of blood collected by EDTA for DNA extraction (frozen directly at ?20°c); 1 tube of 5 ml of blood in dry tube. Serum is frozen at ?20°c for determining serological markers.
Presence of a biobank	Yes
Contents of biobank	Serum DNA
Details of biobank content	Serum bank, DNA bank
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Clinical examinations: handwritten with double-data entry.
Quality procedure(s) used	Consistency request upon entering computer data and following collection of computer data. Management of missing data by returning to source file and/or returning to general practitioner.

	Physician reminder for follow-up visits. Internal quality audit carried out once a year. Patients are informed about the use of their data.
Participant monitoring	Yes
Details on monitoring of participants	Every 3 months when encountering experts within the pathology registry (incidence).
Links to administrative sources	Yes
Linked administrative sources (detail)	Pathology registry

Promotion and access

Promotion

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: comparison and validation of data with other IBD cohorts (USA, Norway). 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