

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

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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 disease, hospitalisation, treatment, complications, death

Scientific investigator(s) (Contact)

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Collaborations

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

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

Sponsor(s) or organisation(s) responsible	CENTRE D'INVESTIGATION CLINIQUE DU CHRU DE LILLE
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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 out as part of an interventional study	No
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Additional information regarding sample selection.	Retrospective. Other bodies active in creating this cohort: CHU, CHG, Independent physicians. Closing date for inclusion: 01/12/2004.
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Database objective

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