

CESAME - Cancer and Increased Risk Associated with Inflammatory Bowel Disease in France

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General

Identification

Detailed name Cancer and Increased Risk Associated with Inflammatory Bowel Disease in France

Sign or acronym CESAME

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation Accord CNIL 784332

General Aspects

Medical area Cancer research

Health determinants Genetic
Nutrition
Social and psychosocial factors

Keywords lymphoma, Health episodes, incidence, mortality

Scientific investigator(s) (Contact)

Name of the director Beaugerie

Surname Laurent

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Unit UMRS-S 707

Organization INSERM - Institut National de Santé et Recherche

Collaborations

Funding

Funding status Mixed

Details PHRC, LIGUE CONTRE LE CANCER AFA, SNFGE,

FERRING

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM - Institut National de Santé et Recherche Médicale
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 Other bodies active in creating this cohort: URC, AFA, ANGH, CREGG, FFCD, GETAID, GFHGNP, SFED, SNCP, SNFGE, TLA REVUE FRANCOPHONE DE GASTRO-ENTEROLOGIE, PHARMACEUTICAL COMPANIES INVOLVED IN THE TREATMENT OF IBD, L'ASSOCIATION FRANÇAISE DES MALADES ATTEINTS DE MICI, REGIONAL FMC GASTROENTEROLOGY ASSOCIATIONS

Database objective

Main objective General objective: To test the hypothesis that the use of immunosuppressants (IS) for inflammatory bowel disease (IBD) leads to an increased risk of lymphoma in a cohort population. Secondary objective: to assess - relative risk associated with IS treatment for all cancers, to assess the standardised incidence rate for all other cancers observed during IBD; -The increased risk of colorectal cancer associated with extensive and former colonic inflammation for ulcerative colitis (UC) and Crohn's disease: - Increased risk of ileal adenocarcinoma associated with chronic ileal inflammation in Crohn's disease; - Evaluation of mortality of patients with IBD diseases and risk factors; - Protective role of salicylates, pregnancy and malformation syndromes.

Inclusion criteria	Subjects with IBD (Crohn's disease, ulcerative colitis, and indeterminate colitis) defined according to the usual diagnostic criteria, who attended consultation at least once between May 2005 and May 2006.
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Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	Multicentric cohort throughout France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	05/2006
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Date of last collection (YYYY or MM/YYYY)	12/2007
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Size of the database

Size of the database (number of individuals)	Greater than 20 000 individuals
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Details of the number of individuals	20819
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Biological data
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Clinical data (detail)	Direct physical measures Medical registration
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Biological data (detail)	Type of samples taken: tumour tissues for cancer cases
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Presence of a biobank	Yes
Contents of biobank	Tissues
Details of biobank content	CANCER TISSUE BANK: LYMPH NODE SAMPLES FOR LYMPHOMA CASES, COLON CANCER
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: 29 months
Links to administrative sources	Yes
Linked administrative sources (detail)	CépiDc

Promotion and access

Promotion

Link to the document	http://www.hal.inserm.fr/CESAME
Description	List of publications in HAL
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=%28cesame+AND+Beaugerie[Author]%29+OR+22157331[uid]
Description	List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams 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