SECSII - Longitudinal Study on Patients with Irritable Bowel Syndrome: Epidemiological Monitoring and Cost

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General

Identification

Detailed name	Longitudinal Study on Patients with Irritable Bowel Syndrome: Epidemiological Monitoring and Cost
Sign or acronym	SECSII
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL approval DR-2014-07 (authorisation request no. 913409); 01 April 2014 CEERB North Paris: No. 13-065: Irritable Bowel Syndrome : an economic and [...]

General Aspects

Medical area	Gastroenterology et hepatology
Health determinants	Iatrogenic Medicine Nutrition Social and psychosocial factors
Keywords	irritable bowel syndrome, abdominal pain, altered bowel habits, direct cost, indirect cost, severity, diagnosis, treatment

Scientific investigator(s) (Contact)

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Organization	APHP

Collaborations

Participation in projects, networks and consortia	Yes
Details	E-cost European project; GENIEUR (www.genieur.eu)

Funding

Funding status	Private
Details	National French Society of Gastroenterology

Governance of the database

Sponsor(s) or organisation(s) responsible	Groupe Français de Neuro-Gastroentérologie (GFNG)
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Société Nationale Française de Gastro-Entérologie (SNFGE)
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Association National des Hépato-Gastroentérologues des Hôpitaux Généraux (ANGH)
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Club de Réflexion des Cabinets et Groupes d'Hépato-Gastroentérologie (CREGG)
Organisation status	Private
Sponsor(s) or organisation(s) responsible	Association des Patients Souffrant du Syndrome de l'Intestin Irritable (APSSII)
Organisation status	Private

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)

Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Patients attending consultation.

Database objective

Main objective	Irritable bowel syndrome (IBS), which involves abdominal pain and altered bowel habits, is a common disease that affects 5% of the population. There is no diagnostic test provided and the treatments used are often ineffective. IBS may significantly reduce quality of life and impact daily activities and work. All of these factors can contribute to increased consultations and treatment and, as such, the overall cost of the disease in France for which there is no recent data. The aim of this cohort is to describe the actual overall cost of IBS by assessing direct costs (examinations, consultations, hospitalisations, reimbursed or non-reimbursed treatment, self-medication, alternative treatments), and indirect costs (work disruption, reduced productivity), assessing the role of factors linked to the disease (IBS type, severity, disease history) and the treatment type (centres of expertise, hospital, practice). This is a multicentric French cohort of IBS patients for carrying out health economics and epidemiological analyses (increased knowledge of prognostic demographic factors, history, comorbidities, predominant symptoms, type of treatment).
Inclusion criteria	- Aged 18 to 75 years old; - Suffering from IBS (ROME-II criteria); - Normal digestive examinations (total colonoscopy and/or normal barium enema for subjects aged 50 or over, proctosigmoidoscopy and/or normal barium enema in people under 50 years old). These examinations should be carried out 5 years prior to enrolment for patients over 50 years old. There is no time limit for patients under 50 years of age. - Satisfactory level of French language comprehension and expression. - Internet access or agreement to send questionnaires by post.

Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France

Data collection

Dates	
Date of first collection (YYYY or MM/YYYY)	2014
Date of last collection (YYYY or MM/YYYY)	2018

Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	500

Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	--
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Patient self-administered questionnaire on quality of life, anxiety, depression, work presenteeism and disruption, as well as healthcare consumption.

Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Data are collected through a secure internet site that was specifically developed for this study and approved by the CNIL (French National Data Processing and Liberties Commission).
Quality procedure(s) used	Real-time monitoring with CRA.
Participant monitoring	Yes
Details on monitoring of participants	Frequency of visits (physician): baseline, 6 months and one year. Frequency of self-administered questionnaires (patient): baseline, 3 months, 6 months, 9 months and 1 year.
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Through publications. Contact the scientist in charge for further information.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only