NEUROPATHIE ENTERIQUE (ENTERIC NEUROPATHY) - Enteric Neuropathy

Head :Bourreille Arnaud, INSTITUT DES MALADIES DE L'APPAREIL DIGESTIF (IMAD). SERVICE DE GASTRO-ENTEROLOGIE ET D'ASSISTANCE NUTRITIONNELLE.

Last update : 05/13/2015 | Version : 1 | ID : 5972

General

Identification

Detailed name	Enteric Neuropathy
Sign or acronym	NEUROPATHIE ENTERIQUE (ENTERIC NEUROPATHY)
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Date of receipt favourable opinion from CNIL: 01/01/2008

General Aspects

Medical area	Gastroenterology et hepatology Neurology
Health determinants	Genetic
Keywords	phenotypic data, demographic data, computerised data bank, biotherapy, steroid dependence, rheumatic, skin, eye and vascular extra-digestive symptoms, hospital stays, immunosuppressants, health events, consultation, diagnosis, surgery, liver

Scientific investigator(s) (Contact)

Name of the director	Bourreille
Surname	Arnaud
Address	44093 NANTES CEDEX
Phone	+ 33 (0)2 40 08 31 52 ou +33 (0)2 40 08 79 25
Email	arnaud.bourreille@chu-nantes.fr
Unit	INSTITUT DES MALADIES DE L'APPAREIL DIGESTIF (IMAD). SERVICE DE GASTRO-ENTEROLOGIE ET D'ASSISTANCE NUTRITIONNELLE.

Organization	UMR INSERM U913 CHU
Collaborations	
Funding	
Funding status	Public
Details	CHU Nantes DRCI (Clinical Research and Innovation Delegation) and AAP DHOS-INSERM
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHU Nantes
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 as part of an interventional study	No
Additional information regarding sample selection.	Prospective Other bodies active in creating this cohort: CHU, INSERM UMR 913 AND CIC-04 GASTROESOPHAGEAL NUTRITION AND NEUROLOGY FIELD
Database objective	
Main objective	General objective: to develop and expand the cohort and enteric neuropathy biological collection for patients with IBD and Parkinson's disease (PD). Secondary objectives: - Transcriptomic study of neuronal and glial plasticity; - Study and classification of neuro-degenerative processes; - Correlation of neuronal damage with clinical parameters and outlook.
Inclusion criteria	Enrolment includes all adult patients with IBD and PD monitored by the CHU in Nantes. Patients will be

	enrolled at time of diagnosis. Patients will be enrolled after disease diagnosis if phenotypic data included in the database are available in the source file. Blood will be taken during sampling in order to monitor patient disease. Biopsy samples will be taken during endoscopic examinations for conventional disease monitoring. Exclusion criteria: underage patients, absence of study participation consent, lost to follow-up, phenotypic data not available from source file, PD patients with no digestive disorder requiring an endoscopy.
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	Regional
French regions covered by the database	Pays de la Loire
Detail of the geography area	Pays de la Loire region
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	100 IBD patients and 30 PD patients were included in the biological collection. These patients are part of the historical cohort. Phenotypic data is entered in the electronic database.
Data	
Database activity	Data collection completed
Type of data collected	Clinical data

	Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at baseline and every 6 months during follow-up. Information collected during clinical examination: items are filled out during interview. Items correspond to those in the database. Patients are followed up every 6 months and an interview is carried out at every additional visit. Item details were previously entered.
Declarative data (detail)	Face to face interview
Details of collected declarative data	Interview questionnaire at baseline and every 6 months during follow-up.
Biological data (detail)	Type of samples taken: blood samples (serum 10 ml and 10 ml whole blood) colonic (x6) and/or gastroesophageal biopsies (x4)
Presence of a biobank	Yes
Contents of biobank	Serum Tissues DNAc/RNAm
Details of biobank content	Serum bank, tissue bank, cNAD from colonic biopsy tRNA
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medicines consumption
Procedures	
Data collection method	Interview: direct input Clinical examinations: direct input Biological analysis: direct input
Quality procedure(s) used	Consistency request after electronic data is recorded. Missing data is managed by returning to source file. Physician reminder for follow-up visits. Subject reminder for follow-up visits. Annual internal quality audit of database with 10% file analysis. Patients are informed about the use of their data.
Participant monitoring	Yes

Details on monitoring of participants	(Indefinite duration)
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams. Access conditions for biological collection are part of the Biobanque Ouest Atlantique (BOA, Western Atlantic Biobank) pending GIS-IBiSA certification request. Data will be available to other institutional research teams under contract. Data may be used by industrial teams. Access conditions for biological collection are part of the Biobanque Ouest Atlantique (BOA, Western Atlantic Biobank) pending GIS-IBiSA certification request. Data will be available to other private research teams under contract with CHU.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only