REPOMSE - Cohort of patients with refractory epilepsy initially admitted to video-EEG monitoring unit

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Last update : 07/25/2014 | Version : 1 | ID : 60180

General

Identification

Detailed name	Cohort of patients with refractory epilepsy initially admitted to video-EEG monitoring unit
Sign or acronym	REPOMSE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL n°910398 - AFSSAPS : B1001-08-40 - CPP : 2010-006-2

General Aspects

Medical area	Neurology Radiology and medical imaging
Keywords	sudden unexpected death in epilepsy (SUDEP), accidents caused by epileptic seizures, status epilepticus, recovery, improvement, stability, hospitalised subjects, Health episodes, death, comorbidities, suicide, progression, aggravation, health system

Scientific investigator(s) (Contact)

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Organization	Inserm
Collaborations	
Participation in projects, networks and consortia	Yes
Funding	
Funding status	Mixed
Details	Programme hospitalier de recherche clinique, les 14 CHU concernés, Ligue Française contre l'Epilepsie, Laboratoires pharmaceutiques EISAI au travers de donations à la LFCE
Governance of the database	
Sponsor(s) or organisation(s) responsible	Hospices civils de Lyon
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.	Prospective
Database objective	
Main objective	General Objective: To determine the main risk factors for sudden unexpected death in epilepsy (SUDEP), focusing on the impact of critical and post-critical apnoea as well as the origin site of a seizure. Secondary objective: to obtain systematic data related to: - inpatient treatment modalities for EGG-video monitoring; - long-term follow-up of

	patients on a medical or medico-economic plan; - results of epilepsy surgery; - serious comorbidities associated with epilepsy (including increased mortality); - Genetic susceptibility factors (systematic genotyping).
Inclusion criteria	Patients with refractory epilepsy admitted to a video-EEG monitoring unit to characterise their seizure type (for surgical treatment for epilepsy or to better identify their epileptic syndrome)

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Multicentric cohort throughout France (14 centres): The 14 centres participating in the study represent the bulk of institutions benefiting from long-term video-EGG monitoring treatment for patients who meet the inclusion criteria

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	06/2010

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	933 (juillet 2013)

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data

Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Paraclinical data (detail)	Imaging and electrophysiology Patients will be included during long-term video-EEG monitoring in order to record and characterise their seizures. This monitoring will provide very precise clinical (video of seizure) and electroencephalographic (scalp EEG see intracranial) information for critical and intercritical events. Using other sophisticated investigative data (MRI, functional MRI, positron emission tomography, ictal SPECT, MEG), this information will be used to establish the probable origin site of seizures and to look at surgical resection of the latter in order to control the disorder. This vital information is key to the phenotypic characterisation of the cohort and requires a significant number of man hours in order to be properly collected and coded. It is particularly relevant concerning the criteria for evaluating the health of the population being examined (especially SUDEP risk).
Biological data (detail)	Type of samples taken: blood sample
Presence of a biobank	Yes
Contents of biobank	DNA
Details of biobank content	DNA bank
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception

Procedures	
Data collection method	Self-administered questionnaire: entry from a paper questionnaire (manual input); Interviews: entry from a paper questionnaire (manual input); Biological analysis: handwritten (manual input)
Participant monitoring	Yes
Details on monitoring of participants	(Indefinite duration)
Links to administrative sources	Yes

Linked administrative sources (detail)	PMSI, CépiDc, CRAM, INSEE database for vital status. Epilepsy database accessible online in order to obtain cohort patient data: GRENAT (National Epilepsy Group Register)

Promotion and access

Promotion

Link to the document	http://www.lfce.fr/Publication_a80.html

Access

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