ESPERA - European observational study on epileptic patients (Requiring at least two Antiepileptic drugs)

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General

Identification

Detailed name	European observational study on epileptic patients (Requiring at least two Antiepileptic drugs)
Sign or acronym	ESPERA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 910087

General Aspects

Medical area	Neurology
Health determinants	Iatrogenic Medicine
Keywords	pharmaco-resistance, observational

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	GSK laboratory

Governance of the database	
Sponsor(s) or organisation(s) responsible	Laboratoire GSK
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	A two-stage stratification method will be used to ensure sufficient number of AEDs resistant patients to be enrolled: a) stratification of the investigators: there are a total number of about 2,000 neurologists in each country of interest. These neurologists can be divided in 3 categories according to the magnitude of their activity in the management of epilepsy : - A first category concerns neurologists with a low activity (less than 5 outpatients a week in consultation) they will not be invited to participate. - A second category concerns neurologists specialised in epilepsy management (epileptologists) who will be identified, either as members of a medical association (French League Against Epilepsy in France) or through their setting in centres specialized in epilepsy (about 20 centres in France and Spain). All epileptologists in this category will be asked to participate. - The third category includes the remaining neurologists. The study will be proposed to a random sample of this last group up to reach the expected number of participating investigators. b) stratification of the patients included: each investigator will be asked to enroll about one AEDs

	resistant in three patients, the other patients being either patients whose AEDs resistance is currently undefined or AEDs responsive patients. The 3 sub-groups of patients included will therefore be as follows: ? AEDs resistant patients in accordance with the criteria established by the ILAE in 2009 (see the note below); ? AEDs responsive patient at inclusion; ? Status currently undefined regarding AEDs resistance at inclusion According to the 2009 ILAE Task Force definition a AEDs resistance is defined as ?failure of adequate trials of two tolerated appropriately chosen and used AEDs schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom?. The seizure freedom is defined by ? freedom from all types of seizures for 12 months or 3 times the preintervention interseizure interval, whichever is longer?
Database objective	
Main objective	To describe the population of adult patients with focal epilepsy currently being treated by an association of at least two antiepileptic medications, in terms of clinical profile, current medical management and seizure control, history of care, referral pathways and quality of life.
Inclusion criteria	? Patient aged ? 18 years, presenting with focal epilepsy with or without secondary generalization; ? Patient currently treated with at least 2 antiepileptic medications in association, for at least 3 months, whether the patient is seizure-free or not; ? Available medical data allowing to specify AEDs responsiveness status (resistant, responsive, or undefined); ? Patient who has agreed to participate after having read the information letter.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population

Gender	Male Woman
Geography area	International
Detail of the geography area	France and Spain

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	800

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
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	The data collected will circulate from the investigators to the data management center via a depersonalized paper questionnaire (medical data).

	The other data collected will circulate from the patients to the data management center via the depersonalized paper questionnaires (self-questionnaires) sent through the mail (return postage paid envelope).
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only