EULEVp - Effectiveness and Use of Levetiracetam of pediatrics in real life

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General

Identification

Detailed name	Effectiveness and Use of Levetiracetam of pediatrics in real life
Sign or acronym	EULEVp
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS 07.072, CNIL 904498

General Aspects

Medical area	Neurology
Health determinants	Iatrogenic
Keywords	Levetiracetam, child, effectiveness, prescribing patterns, pharmaco-epidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Mixed
Details	Laboratoire UCB Pharma (soutien inconditionnel) - UCB Pharma (unconditional support)

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM
Organisation status	Public

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	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.	This observational study was conducted among a sample of hospital and non-hospital neurologists who were to retrospectively include 250 patients younger than 16 who had a first prescription of levetiracetam between 1 October 2006 and 31 March 2007 and follow these for 12 months from initiation.

Database objective

Main objective	The objectives of this study were to describe the children initiating treatment with levetiracetam, the prescribing patterns, and to evaluate the effectiveness of levetiracetam in a real situation in terms of treatment retention for one year.
Inclusion criteria	Patient aged under 16 years; Obtainment of consent from the guardian of the child; patient having initiated treatment with levetiracetam between 01/10/2006 and 31/03/2007 (whether or not the treatment was continued), and having never been previously treated with levetiracetam; patient who may be followed over the following 12 months; Patient not participating in a clinical trial (Huriet-Sérusclat).

Population type

Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Hospital and non-hospital neurologists in metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2007
Date of last collection (YYYY or MM/YYYY)	2008

Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	156
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Patients included were the subject of collection of indirectly personal medical data (patient questionnaire completed by the neurologist) at inclusion, at each follow-up visit, and and at one year of follow-up or in case of discontinuation of levetiracetam data will be collected for all patients.
Participant monitoring	Yes
Details on monitoring of participants	Levetiracetam-treated patients were followed for a period of one year (from date of levetiracetam initiation).
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=eulevp
Description	List of publications in Pubmed

Access	
Terms of data access (charter for data provision, format of data, availability delay)	A final study report was submitted to the funder. The final study report and scientific communications (posters, papers, ...) are validated by the study Scientific Committee. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the funder. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only