EULEV - Effectiveness and Use of Levetiracetam in Real Life

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General

Identification

Detailed name	Effectiveness and Use of Levetiracetam in Real Life
Sign or acronym	EULEV
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS 04.198, CNIL 904498

General Aspects

Medical area	Neurology Psychology and psychiatry
Health determinants	Iatrogenic Medicine
Keywords	Levetiracetam, prescribing patterns, effectiveness, pharmacoepidemiology, 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) - Inserm

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.	Two parallel and complementary studies have been implemented. An observational study was conducted among a sample of hospital and non-hospital neurologists who were to retrospectively include over two periods 1000 patients who had received a first prescription of levetiracetam (between 1 January and 31 August 2005, or between January 1 and August 31, 2006 for the second period). For each inclusion period, all neurologists registered in the "Cegedim" database were invited by post to participate in the study.In parallel, a study based on the EPIB sample from the SNIIRAM database was performed using two extractions of anonymised data of patients who had at least one reimbursement of levetiracetam between 1 July 2004 and 31 August 2005 for the first extraction and between 1 July 2005 and 31 August 2006 for the second.The study based on the EPIB sample allowed the verification of the field study sample validity and to collect information independently of the field study.
Database objective	
Main objective	The objectives of this study were to describe patients initiating treatment with levetiracetam, the prescribing patterns, and to evaluate the effectiveness of levetiracetam in a real-life situation in terms of treatment retention over one year.
Inclusion criteria	Patients who initiated treatment with levetiracetam between 01/01/2005 and 31/08/2005 or between 01/01/2006 and 31/08/2006 (irrespective of whether or not treatment was continued), and having never previously been treated with levetiracetam; patient agreeing to participate; patient can be followed over the next 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) 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	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)	2006
Date of last collection (YYYY or MM/YYYY)	2008

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	858

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	Included patients were the subject of collection of indirectly personal medical data (patient questionnaire completed by the neurologist) at inclusion, at each follow-up visit, 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=eulev%20NOT%20eulevp&cmd=correctspelling
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, articles, ...) 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