

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 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