EVALUATING THE OCCURRENCE OF ADVERSE EVENTS AMONG PEDIATRIC PATIENTS EXPOSED TO INTRAVENOUS LACOSAMIDE (VIMPAT®) USING REAL WORLD DATA

First published: 30/01/2020

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Study Finalised

Administrative details

EU PAS number

EUPAS32597

Study ID

45234

DARWIN EU® study

No

Study countries

United States

Study description

This will be a retrospective cohort study that will use data from the PEDSnet database to estimate the incidence of select medical events for 8 System Organ Classes and 3 Standardized MedDRA Queries terms and specific medical events included in these broad categories, and examine the effect of increasing intravenous (IV) Lacosamide (LCM) loading dose on the incidence of these select medical events. The study will also compare the incidence of the selected medical events in pediatric patient (aged ≥ 1 month <17 years) treated with higher IV LCM doses (including UCB's defined loading dose) to the incidence of these events in pediatric patients treated with a recommended initial/maintenance IV LCM dose.

Study status

Finalised

Research institutions and networks

Networks

PEDSNet

Contact details

Study institution contact

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent

according to Section 4a of the German Federal Act on Data Protection is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results Personal identifiable data of lead investigator are not published here, as consent according to Section 4a of the German Federal Act on Data Protection is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/09/2019

Actual: 18/09/2019

Study start date

Planned: 31/01/2020

Actual: 31/01/2020

Data analysis start date

Planned: 01/03/2020

Date of final study report

Planned: 30/06/2020

Actual: 14/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB BIOPHARMA SRL

Study protocol

Study-protocol amd1_redacted.pdf (2.38 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to estimate the incidence of the select medical events of interest, those being the 8 System Organ Classes (SOCs) and 3 Standardized MedDRA Queries (SMQs) listed below, in pediatric patients after treatment with higher intravenous (IV) Lacosamide (LCM) doses, compared to pediatric patients treated with recommended initial/maintenance IV LCM dose.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

LACOSAMIDE

Population studied

Short description of the study population

The study population will consist of the following two mutually exclusive cohorts:

 Pediatric patients treated with higher IV LCM doses (including UCB's defined loading dose), regardless of diagnostic code i.e. patients do not have to have a formal diagnosis of specific types of epilepsy and they may include children with SE caused by other conditions.

 Pediatric patients treated with recommended initial/maintenance IV LCM dose regardless of diagnostic code i.e. patients do not have to have a formal diagnosis of specific types of epilepsy and they may include children with SE caused by other conditions. These two groups are defined by the proposed alternative higher initial dosage (first dose, first treatment in observed episode) and the recommended initial dosage (first dose, first treatment in observed episode) and patients remain in that group thereafter. Switching is not allowed at any time.

Patients will be initially identified using the following study criteria.

Inclusion Criteria

• Patients with at least one iv LCM administration (earliest administration defines index date)

• At least 1 encounter with iv LCM administered between ages of ≥1 month and <17 years

Exclusion Criteria

• No exposure to either oral or iv LCM within the 3 months prior to the index date

o In the case of patients < 90 days of age, no prior LCM ever in the record

A separate cohort for patients < 30 days old is established with the following criteria.

Neonates Inclusion Criteria

• Patients with at least one iv LCM administration (earliest administration defines index date)

• At least 1 encounter with iv LCM administered before 30 days of age.

Neonates exclusion criteria

• No exposure to either oral or iv LCM prior to the index date

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Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)

Estimated number of subjects

681

Study design details

Outcomes

Incidence rate and ratio of cardiac disorders, general disorders, administration site conditions, injury, poisoning, procedural complications, skin and subcutaneous tissue disorders, drug reactions with eosinophilia, systemic symptoms syndrome, severe cutaneous adverse reactions, hypersensitivity, nervous system disorders, metabolism and nutrition disorders and psychiatric disorders etc. Incidence rate and ratio of atrioventricular block, atrioventricular block complete, atrioventricular block first degree and second degree, arrhythmia, bradyarrhythmia, bradycardia, cardiac fibrillation, cardiac flutter, tachyarrhythmia, atrial fibrillation, atrial flutter, cardiac arrest, torsade de pointes, ventricular arrhythmia, fibrillation and tachyarrhythmia, palpitations,

chest pain etc.

Data analysis plan

For the baseline characteristics, mean, standard deviation, median, and quartiles will be used to describe continuous variables, whereas frequencies and percentages will be used to describe categorical variables. The baseline characteristics will include demographic characteristics, number of previous and concomitant Antiepileptic drug, and concomitant medications prescribed prior to the index date, prevalence of comorbidities, preexisting medical events of interest, medical procedures such as EEG, and dosage of intravenous Lacosamide. Incidence rate ratios will be used to compare event rates between groups.

Documents

Study results

ep0147-bodytext-redacted.pdf (1.65 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

PEDSNet, pediatric electronic medical records from secondary care source.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No