A European non-interventional study to understand the criteria used and the time required for the clinical diagnosis in participants with refractory epilepsies associated with developmental delay European Non-interventional Study on Refractory Epilepsy with Developmental Delay (ENSURED)

First published: 14/01/2020

Last updated: 14/01/2020

Study Planned

Administrative details

EU PAS number

EUPAS32984

Study ID

32985

DARWIN EU® study

No

Study countries

Belgium

France

Germany

Ireland

Italy

Spain

Sweden

United Kingdom

Study status

Planned

Research institutions and networks

Institutions

Zogenix International

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Moyo Tobun ClinStudyInfo@zogenix.com

Study contact

ClinStudyInfo@zogenix.com

Primary lead investigator

Moyo Tobun

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/12/2019

Study start date
Planned: 01/01/2020

Date of final study report
Planned: 31/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zogenix International Ltd.

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To understand the criteria used and the timerequired for the clinical diagnosis in participants with refractory epilepsiesassociated with developmental delay

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, retrospective data collection (manual Medical Chart Review)

Study drug and medical condition

Medical condition to be studied

Epilepsy

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1.500

Study design details

Outcomes

-Proportion of participants with and without syndromic diagnosis-Criteria used for the diagnosis of clinical syndromes for participants with refractory epilepsy with development delay-Proportion with successful treatment (defined as meaningful clinical response, in clinician’s opinion), if documented in the

participant notes.-Time to diagnosis of clinical syndromes for participants

Data analysis plan

This study is a retrospective analysis. For this reason epidemiological methods will be employed for data analyses. All analyses will be performed in an exploratory sense. Since there are no confirmatory analyses planned,hypotheses are not formulated. Data will be analyzed using descriptive statistics. Summaries will be presented by total, age group and country if applicable.

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)

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