DARWIN EU® - Neonatal seizures: Incidence, prevalence, patient characterisation, and treatments in European countries

First published: 10/11/2025

Last updated: 10/11/2025

Study   Ongoing

Administrative details

EU PAS number

EUPAS1000000822

Study ID

1000000822

DARWIN EU® study

Yes

Study countries

- [ ] Finland
- [ ] France
- [ ] Hungary

☐ Norway

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

☐ Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution   Educational Institution   ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium
☐ Croatia
☐ Denmark
☐ Estonia
☐ Finland
☐ France

- ☐ Germany
- ☐ Greece
- ☐ Hungary
- ☐ Italy
- ☐ Netherlands
- ☐ Norway
- ☐ Portugal
- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Dina Vojinovic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/09/2025

Actual: 24/09/2025

Study start date

Planned: 31/10/2025

Actual: 31/10/2025

Date of final study report

Planned: 27/02/2026

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

1. To estimate the incidence and prevalence of seizures in neonates.

2. To characterise patients' demographic and clinical profile at the time of diagnosis, including:

- sex

- age at diagnosis

- gestational age

- weight at birth

- Symptoms

- diagnostic tools (EEG, Video EEG, etc.)

- comorbidities/concurrent conditions, including those presenting a high risk for seizure development hypoxic-ischemic encephalopathy, stroke or haemorrhage, infections, cortical malformations, errors of metabolism (acute and inborn), and genetic aetiologies.

3. To characterise treatments received for the primary diagnosis of seizures in neonates, including standard of care, treatment pattern and duration of treatment.

4. To describe short, mid and long-term outcomes (including survival, related diagnosed conditions such as neurodevelopmental, neurological [e.g. epilepsies, cerebral palsy]) at 1 month of discharge, 2 years of age and 6-7 years of age.

Data management

ENCePP Seal

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No