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

First published: 10/11/2025

Last updated: 09/04/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000822

Study ID

1000000822

DARWIN EU® study

Yes

Study countries

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

Norway

Study description

Neonatal seizures are among the most common neurological emergencies in newborns and are typically
symptomatic of acute central nervous system insults, such as hypoxic-ischaemic encephalopathy, stroke, or
infection. Diagnosis is challenging due to the predominance of electrographic-only seizures, requiring
electroencephalogram (EEG) confirmation. This study aims to generate real-world evidence on the
occurrence, clinical presentation, and treatment of neonatal seizures across European data sources to
support regulatory decision-making.

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

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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: 15/05/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-014_Neonatal seizures_V2.0.pdf (1.53 MB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 5 data sources from 5 countries
across Europe and in 4 EU member states.

Main study objective:

1. To estimate the incidence and prevalence of seizures in neonates.
2. To characterise the demographic and clinical profile of neonates at the time of seizure diagnosis
including:
• Sex
• Age
• Gestational age
• Birth weight
• Clinical manifestations of seizures
• Diagnostic tools used (e.g., EEG) and, where feasible, availability of EEG modalities (such as
conventional EEG, amplitude EEG, or video EEG)
• Comorbidities and concurrent conditions, including those presenting a high risk for seizure
development, such as hypoxic-ischaemic encephalopathy, stroke or haemorrhage, infections,
cortical malformations, errors of metabolism (acute and inborn), and genetic aetiologies
• Comedication
3. To characterise i) treatment received from the primary diagnosis of seizures in neonates, ii)
treatment patterns, and iii) duration of treatment.

4. To describe short-, mid-, and long-term outcomes among neonates diagnosed with seizures
(including survival and related diagnosed conditions such as neurodevelopmental and neurological
disorders) at 3 months, 6 months, 2 years, and 6–7 years of age.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medical condition to be studied
Neonatal seizure

Population studied

Short description of the study population
Descriptive epidemiology study (objective 1): The study population will include all neonates, defined as
infants from birth to 28 days of life, present in the data source between 1 January 2014 and 31 December
2024 (or the latest date available).
Characterisations (objectives 2, 3(i, ii) and 4: The study population will include all neonates with a first
recorded diagnosis of seizures during the neonatal period, present in the data

source between 1 January
2014 and 31 December 2024 (or the latest date available). For outcome analyses (objective 4), only
neonates diagnosed with seizures at least 90 days prior to the end of data availability in each data source
will be included to ensure sufficient follow-up. Additionally, for objective 4, eligible neonates must have no
prior recorded diagnosis of the outcome condition of interest before the index date (date of seizure
diagnosis).
Drug utilisation study (objective 3(iii)): The study population will include neonates diagnosed with seizures
who initiate anti-seizure pharmacological treatment during the neonatal period and who are present in the
data source between 1 January 2014 and 31 December 2024 (or the latest date available). To ensure a new
user design, eligible neonates must have no prior record of anti-seizure medication use before the index
date (date of treatment initiation).

Age groups

- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)

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 source(s)

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Clinical Data Warehouse of the Bordeaux University Hospital

Semmelweis University Clinical Data

Health Impact - Swedish Population Evidence Enabling Data-linkage

UK National Neonatal Research Database

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