Comparative Study: Long-Term Neurodevelopmental Outcomes in Neonates Treated with Lacosamide vs Other Antiseizure Medications for Neonatal Seizures

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000618

Study ID

1000000618

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Contact details

Study institution contact

UCB Cares UCBCares@ucb.com

Study contact

UCBCares@ucb.com

Primary lead investigator

Moninder Kaur

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/05/2025

Study start date

Planned: 16/06/2025

Actual: 17/06/2025

Date of final study report

Planned: 15/02/2026

Actual: 18/02/2026

Sources of funding

More details on funding

UCB Biopharma SRL

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

EP0223

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Study drug and medical condition

Medicinal product name, other

Lacosamide

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

LACOSAMIDE

Anatomical Therapeutic Chemical (ATC) code

(N03AX18) lacosamide

lacosamide

Medical condition to be studied

Neonatal seizure

Population studied

Age groups

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

Study design details

Comparators

Other Antiseizure Medications for Neonatal Seizures.

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes