Pilot study on efficacy and safety of video-EEG monitoring to early identify newborns affected by mild hypoxic-ischemic encephalopathy who may benefit from therapeutic hypothermia: correlation between early video-EEG monitoring and 24-months neurodevelopmental outcome in treated and non-treated newborns.

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Study Planned

Administrative details

EU PAS number

EUPAS106301

Study ID

106302

DARWIN EU® study

No

Study countries

Italy

Study status

Planned

Contact details

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Study contact

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Primary lead investigator

Maurizio Radicioni

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/09/2023

Study start date

Planned: 27/09/2023

Date of final study report

Planned: 31/10/2025

Sources of funding

- Other

More details on funding

University Hospital of Perugia

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

Main study objective:

The main objective of this study is to determine in a cohort of newborns affected by mild hypoxic ischemic encephalopathy, treated or non-treated with therapeutic hypothermia, the correlation between early video-EEG monitoring, performed within 6 hours of birth, and 24-months neurodevelopmental

outcome, assessed using the Griffiths III Developmental Scales.

Study Design

Non-interventional study design

Other

Population studied

Age groups

- Term newborn infants (0 – 27 days)
- Children (2 to < 12 years)

Estimated number of subjects

40

Study design details

Outcomes

The correlation between early video-EEG monitoring, performed within 6 hours of birth, and 24-months neurodevelopmental outcome, assessed using the Griffiths III Developmental Scales, in a cohort of newborns affected by mild hypoxic ischemic encephalopathy, treated or non-treated with therapeutic hypothermia.

Data analysis plan

The Shapiro-Wilk test will be used to assess the normal distribution of variables and, if they will be asymmetric, the Mann–Whitney's U-test will be applied for

comparisons of non-normally distributed continuous and discrete variables. The Chi-square test with Yate’s continuity correction and Fisher’s exact test will be used for the comparisons of categorical variables. Correlations will be checked using the Spearman’s rho correlation coefficient. Kruskal-Wallis and Mann-Whitney U post hoc tests, positive predictive values (PPV) and negative predictive values (NPV) will be analyzed to explore differences between neonatal mild HIE classification and v-EEG classification with developmental score at 24 months using the Griffiths III mental development scales. All statistical analysis will be performed using IBM-SPSS® version 26.0 (IBM Corp. Armonk, NY, USA, 2019). In all analyses, a two-sided p-value < 0.05 will be considered significant.

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)

Other

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