Amplitude integrated electroencephalography as a prognostic value of neurodevelopment in preterm newborns.

First published: 08/06/2020

Last updated: 23/02/2022

Study Planned

Administrative details

EU PAS number

EUPAS35709

Study ID

45926

DARWIN EU® study

No

Study countries

Lithuania

Study description

Over the last decade, the survival of premature babies has improved. Such infants are still affected by dangerous complications occurring during the neonatal period that often cause brain damage. It requires more specialized monitoring of brain function during this critical period. In recent years, many studies on very premature infants have shown that aEEG has a high predictive value for both short-term and long-term outcome. Most recent studies have shown that an aEEG performed in the early hours or during the first days or weeks of life can predict the neurodevelopment of preterm infants at 1 year of corrected age (Bayley Scale). The aim of our study is to determine the prognostic value of amplitude integrated electroencephalography (aEEG) recorded during the neonatal period for the psychomotor development of very preterm infants at the 12-month corrected age. Inclusion Criteria:Patients must meet all the following criteria to be eligible for this study:1. All infant from 22 to 31 week of gestation age, who were born and treated in Hospital Of Lithuanian University Of Health Sciences, Kaunas Clinics.2. The consent of both parents was obtained.Exclusion Criteria:Patients meeting any of the criteria below will not be included in this study:1. There is no written consent from both parents.2. Multiple developmental defects and chromosomal abnormalities, metabolic diseases.3. Progressive post-hemorrhagic hydrocephalus.It is planned to collect the number of subjects: 200.Duration of the study 3 years.

Study status

Planned

Research institutions and networks

Institutions

Lithuanian University Of Health Scinces

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Kristina Stuikiene kristocka@gmail.com

Study contact

kristocka@gmail.com

Primary lead investigator

Rasa Tameliene

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2020

Study start date

Planned: 09/06/2020

Data analysis start date

Planned: 01/09/2022

Date of interim report, if expected
Planned: 31/12/2022

Date of final study report
Planned: 31/12/2023

Sources of funding

- Other

More details on funding

Lithuanian University Of Health Sciences, Hospital Of Lithuanian University Of Health Sciences, Kaunas Clinics., Lithuanian Science Council

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:

Clinical trial

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The aim of our study is to determine the prognostic value of amplitude integrated electroencephalography recorded during the neonatal period for the psychomotor development of very preterm infants at the 12-month corrected age.

Study Design

Clinical trial randomisation

Non-randomised clinical trial

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)

Estimated number of subjects

200

Study design details

Data analysis plan

Amplitude integrated electroencephalography has a high predictive value for both short-term and long-term outcome. It will be possible to provide more help for family of the premature baby, to refer to appropriate professionals. Amplitude electroencephalography provides a minimal intervention outcomes. Subjects will not be given any additional medications. To keep the study confidential, subjects will be given an identification number.

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

Data sources (types), other

Prospective patient-based data collection

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