Continuous EEG registration and surveillance at the NICU in neonates with hypoxic-ischemic encephalopathy

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Is continuous EEG registration with a 9 and 21 channel EEG with SL detection an approved method for the detection of seizures in term neonates with perinatal hypoxia-ischemia? What are the sensitivity and the false positive rate of these methods in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON29983

Source
ToetsingOnline

Brief title
cEEG in neonates with hypoxic-ischemic encephalopathy

Condition

- Seizures (incl subtypes)

Synonym
lack of oxygen during birth, perinatal asphyxia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EEG, hypoxic-ischemic encephalopathy, neonate

Outcome measures

Primary outcome

Analysis:

Sensitivity and false positive rates will be calculated for each detection method. The visual inspected EEG will be used as gold standard and will be compared with the 9 and 21 channel EEG with SL detection and the practical standard, the aEEG. Furthermore, the correlation between the detection method will be assessed with the Spearman Ranks. A p value <0.05 will be designated as statistically significant.

Secondary outcome

na

Study description

Background summary

Epileptic seizures are frequently encountered in term neonates with perinatal hypoxia-ischemia. Since a considerable proportion of these seizures is not detected clinically, and early detection and treatment can improve prognosis positively, it is important to have a sensitive, bedside monitoring system for the detection of seizures.
Visual inspection of the 21 channel EEG is the gold standard for the detection of seizures, however, in daily care situations it is not suitable for continuous bedside monitoring. For that reason the amplitude-integrated EEG (aEEG) has been used in NICUs. The aEEG is a 2 channel EEG with compression in time. Based on pattern recognition the back ground pattern will be judged and the presence of seizures will be monitored. Although it is a practical monitor, it has been shown that not all type of seizures are being recognized by clinicians who daily work with this aEEG. In 2002 the synchronization likelihood (SL), a measure of nonlinear interdependencies between time series

has been introduced by Stam and Van Dijk. This method characterizes detection of dynamic processes of neuronal networks and their interactions. When a certain threshold has been reached it could indicate the presence of a seizure in neonatal EEGs with a sensitivity of 65,9% and a specificity of 89,8%.

Study objective

Is continuous EEG registration with a 9 and 21 channel EEG with SL detection an approved method for the detection of seizures in term neonates with perinatal hypoxia-ischemia? What are the sensitivity and the false positive rate of these methods in comparison to the visual inspected EEG and the aEEG?

Study design

Methods:
- EEG registratration during 22 h with an EEG apparatus from the Clinical Neurophysiological (CNP) unit. Scalp EEG electrodes are placed by the CNP technicians.
- Blinded EEG registration, visual inspection afterwards by 2 clinical neurophysiologists with a scoring system during every 10 minutes; score 0: no epileptic activity, score 1: epileptic activity. Consensus agreement, when needed.
-SL detection using the 9 and 21 channel EEG (Fp1, Fp2, C3, C4, T3, T4, O1, O2, Cz). An event will be scored when during 20 seconds a certain threshold has been
reached, preceded by a 20 second period below the threshold value. Scoring system every 10 minutes: score 0: no registered events, score 1: one or more registered events.
- During the same time period an aEEG will be registered, on which clinical treatment of the seizures will take place, as usual. Two neonatologists will perform blinded inspection of the aEEG, based on pattern recognition afterwards. Score 0: no epileptic activity, score 1: epileptic activity. Consensus agreement, when needed.

Study burden and risks

The child will be connected to an extra monitor for 22 hours. There will be no increased burden for the patient.
With this research additional information can be gained about potential bedside brain monitor techniques to identify epileptic seizures earlier and objectively. In the near future other children may be treated earlier and more effective with anti-convulsive drugs to improve long term outcome after perinatal asphyxia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Inclusion criteria: neonates with gestational duration * 35 weeks with an arterial umbilical pH < 7,00 or an Apgar score * 5 at 5 minutes, present within 24 h after birth at the neonatal intensive care unit of the VU medical center.

Exclusion criteria

Premature neonates; Suspected chromosomal/syndromal abnormalities or metabolic disturbances. Neonates with a skull defect. Inability from the Clinical Neurophysiological (CNP) unit to register the EEG.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13358.029.06