NeoGuard: A neonatal EEG monitor with real-time, bedside data visualization and automated decision support.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Observational non invasive

Summary

ID

NL-OMON38914

Source
ToetsingOnline

Brief title
NeoGuard studie

Condition

- Encephalopathies

Synonym
asphyxia = Oxygen depletion during birth and seizures= fits

Research involving
Human

Sponsors and support

Primary sponsor: UZ Gasthuisberg Leuven
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: automated, EEG, monitor, neonatal

Outcome measures

Primary outcome

To develop a first neonatal, fully automated and continuous brain monitoring to be used in the daily practice.

The automated seizure detector diagnoses seizures with a sensitivity of more than 85% and less than 1 false alarm per 3 hours.

With automated background EEG grading, the prediction of short term outcome (on basis of MRI scores)and long term outcome (on basis of follow-up at two years) can be made with a sensitivity of more than 85% and specificity of more than 80%.

The following questions will be answered: is the software for automatic detection of seizures valuable? Therefore the alarms will be compared with the expert labelling of seizures seen on the classical EEG

Objective quantification of the background EEG is important. The goal is to define important patterns in the background EEG (e.g. sleep-wake cycli, bursts, burst suppression, entropy measures, *).

Secondary outcome

-not applicable

Study description

Background summary

The rationale of this project is thus to address the main problems with infant EEG at this moment. These problems are the application of the EEG electrodes, manual (subjective) interpretation of the signals and the around the clock availability of EEG experts being too difficult and too time consuming for routine use.

Study objective

Hereto, the project wants to meet the following goals:
1. To produce an EEG instrument for continuous brain monitoring, the NeoGuard, enabling automated detection of neonatal seizures and abnormalities in the EEG background pattern. The neonatal nurse or clinician should be able to use the instrument after a short instruction workshop, although verifying automated detections with the raw EEG signal by a supervising expert clinical neurophysiologist will remain preferable.
2. To validate the automated seizure detection program and to validate the background EEG classification program by comparing it with expert EEG interpretation, the extent of brain damage on MRI and psychomotor development of the patients. This will happen in the neonatal intensive care units in Leuven, Antwerp and Rotterdam.

The clinical study will focus on the term infant with encephalopathy.
Once the project is finished we would like to provide different major neonatal units in Flanders (Leuven, Antwerp, Brussels) as well as the EMC Rotterdam with a prototype of the NeoGuard. After a validation study, also large maternity units will be provided with a NeoGuard, coupled with one or more workshops.

2 hypotheses will be tested:
1.The automated seizure detector diagnoses seizures with a sensitivity of more than 85% and less than 1 false alarm per 3 hours.
2. With automated background EEG grading, the prediction of short term outcome (on basis of MRI scores)and long term outcome (on basis of follow-up at two years) can be made with a sensitivity of more than 85% and specificity of more than 80%.

Study design

All babies that fulfill specific criteria will be admitted to the study after parenteral consent. The study will be started as quick as possible in order to collect the data as close to birth as possible.
Treatment of convulsions will be according to the choice of the attending

physician. However, the anticonvulsants will be noted in the data.
The data that will be collected are: CFM (cerebral function monitoring), EEG, MRI performed between day 4 and 10.
At the age of 2 years a follow-up examination will be performed. This will be a Bailey 3 PDI and MDI. An earlier follow-up (AIMS or TIMP) is planned between 4 and 6 months.
The data will be kept on a disk and sent to the central server (KU Leuven), from where further studies can be performed.
Before the start of the measurements, ethical consent will be asked at the parents. When the parents are not there, ethical consent to use the data can be asked as soon as possible. As the investigations are not different than the classical investigations done in children with peripartal asphyxia and no intervention is done, this can be asked after the start of the EEG if it is not possible otherwise.
After collecting the patient data, automated quantification of the EEG pattern will happen.

Study burden and risks

The patients included in the study won't be treated otherwise than non-included patient. The only difference is that the EEG is made with 17 electrodes in stead of 8 or 12 electrodes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Term babies with an umbilical pH less than 7,1
APGAR score less than 6 at 5 minutes
Thompson score more than 4.
Term babies with clinical diagnosis of neonatal seizures

Exclusion criteria

postmenstrual age less than 36 weeks, or postmenstrual age more then 36 weeks and at least one of the other criteria not fulfilled

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-03-2014
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL43296.078.13