The effect of treatment of neonatal electrographic seizures, detected with the continuous cerebral function monitoring, with respect to occurrence of postneonatal epilepsy and neurodevelopmental outcome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24610

Source
Nationaal Trial Register

Brief title
SuSeQue (subclinical seizure question)

Health condition

neonatal seizures in fullterm infants following perinatal asphyxia

Sponsors and support

Source(s) of monetary or material Support: Nederland Epilepsie Fonds (NEF)
Dutch Epilepsy Foundation

Intervention

Outcome measures

Primary outcome

1. What is the number of electrographic seizure discharges missed if you do not monitor continuously;

2. Does instantaneous treatment of electrographical seizures lead to:

a. A reduction of seizure discharges;

b. Less damage on the neonatal MRI.

Secondary outcome

Does treatment of neonatal seizures lead to a reduced risk of postneonatal epilepsy (PNE) and d) an improved neurodevelopmental outcome at 24 months.

Study description

Background summary

Neonatal seizures are commonly seen following perinatal asphixia. Since the introduction of the continuous bedside simplified EEG monitoring devices, it has become clear that subclinical seizures occur in about 50-60% of all neonatal seizures.
As yet it is not known whether treatment of these subclinical seizures is necessary and will improve longterm outcome.
Treatment of neonatal seizures is a challenge and the most commonly used anti-epileptic drugs are only effective in about 50% of the cases.
To resolve the problem whether treatment of subclinical seizures is required or unnecessary and maybe even deleterious to the developing brain, a randomised controlled trial (RCT) is performed.
In the randomised trial infants will be either treated with antiepileptic drugs when they have clinical as well as subclinical seizures, as detetected on the amplitude integrated EEG.
In the other arm, only clinical seizures will be treated and the aEEG will record but will be blinded.

Study objective

We hypothesize that without continuous EEG registration, subclinical electrographic seizures will be missed. Repetive ictal seizures and a sublcinical status epilepticus may be deleterious to the immature brain. On the other hand the use of antiepileptic drugs may also have adverse effects, especially to the developing brain.

Study design

N/A

Intervention

Following initiation of aEEG registration and the occurrence of the first subclinical seizure, and following parental consent, the infant will be randomised to group A (treatment of clinical as well subclinical seizures as detetected on the aEEG) or group B (the aEEG will be blinded, and only clinical seizures will be treated;
Intermittent standard EEG can be performed and in case the EEG shows a status epilepticus this can be treated, but in case a subclinical seizure is seen on the standard EEG, this will not be treated with anti-epileptic drugs).

Contacts

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Eligibility criteria

Inclusion criteria

Fullterm infants admitted to the neonatal intensive care unit, within the first 24 hours after birth with subclinical seizures on the aEEG, in 8 Dutch and 3 Belgium centres.

Exclusion criteria

Preterm infants (<37 wks GA) and fullterm infants with neonatal seizures admitted after the

first 24 hours after birth. Infants with chromosomal disorders, congenital anomalies and meningitis.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2003
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
Application type:	First submission

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
NTR-new	NL268
NTR-old	NTR306
Other	: N/A
ISRCTN	ISRCTN61541169

Study results

Summary results

Van Rooij LCM, Toet MC, Rademaker MCA, Groenendaal, de Vries LS. Cardiac arrhythmia in Neonates Receiving Lidocaine as Anticonvulsive Treatment. Eur J Pediatr 2004Eur J Pediatr. 2004;163:637-41.

van Rooij LG, Toet MC, Osredkar D, van Huffelen AC, Groenendaal F, de Vries LS.Recovery of amplitude integrated electroencephalographic background patterns within 24 hours of perinatal asphyxia.Arch Dis Child Fetal Neonatal Ed. 2005;90:F245-51.

Toet MC, Groenendaal F, Osredkar D, van Huffelen AC, de Vries LS.Postneonatal epilepsy following amplitude-integrated EEG-detected neonatal seizures Pediatr Neurol 2005; 32:241-7