

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.

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 11/08/2008	Condition category Pregnancy and Childbirth	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof L.S. de Vries

Contact details
University Medical Center Utrecht
P.O. Box 85090
Utrecht
Netherlands
3508 AB
l.devries@wkz.azu.nl

Additional identifiers

Protocol serial number
NTR306

Study information

Scientific Title

Acronym

SuSeQue (subclinical seizure question)

Study objectives

We hypothesise that without continuous Electroencephalogram (EEG) registration, subclinical electrographic seizures will be missed. Repetitive ictal seizures and a subclinical 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Neonatal seizures

Interventions

Following initiation of aEEG registration and the occurrence of the first subclinical seizure, and following parental consent, the infant will be randomised to:

1. Group A: treatment of clinical as well subclinical seizures as detected on the aEEG
2. 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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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:

2.1. A reduction of seizure discharges

2.2. Less damage on the neonatal Magnetic Resonance Imaging (MRI)

Key secondary outcome(s)

Does treatment of neonatal seizures lead to a reduced risk of Post-Neonatal Epilepsy (PNE) and an improved neurodevelopmental outcome at 24 months.

Completion date

01/07/2007

Eligibility

Key inclusion criteria

Full term 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.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Preterm infants (less than 37 weeks Gestational Age [GA]) and full term infants with neonatal seizures admitted after the first 24 hours after birth

2. Infants with chromosomal disorders, congenital anomalies and meningitis

Date of first enrolment

01/07/2003

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre

University Medical Center Utrecht
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Charity

Funder Name

Dutch Epilepsy Foundation (NEF) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration