ISRCTN61541169 https://doi.org/10.1186/ISRCTN61541169

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

Registration date
20/12/2005

Last Edited
11/08/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

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

Overall study start date
01/07/2003

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

Age group
Neonate

Sex
Both

Target number of participants
120

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)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Charity

Funder Name
Dutch Epilepsy Foundation (NEF) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration