Studies on electrophysiologic maturation of the premature brain: small for gestational infants and appropriate for gestational age infants.

No registrations found.

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

Summary

ID

NL-OMON21560

Source NTR

Brief title N/A

Sponsors and support

Primary sponsor: N/A Source(s) of monetary or material Support: MMC Veldhoven

Intervention

Outcome measures

Primary outcome

Quantitive analysis of EEG data:

i.e. Burst lenght, interburst length, quantitative aspects of bursts.

Secondary outcome

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Follow up examinations at 2 years and 6 years of age.

Study description

Background summary

In order to prevent adverse neurological outcome in very low birth weight infants, insight in normal brain development and identification of circumstances that damage normal brain development is warranted. Polysomnographic patterns reflect functional brain maturation and are correlated with neurological outcome in preterm infants.

Because of the expertise at the Maxima Medical Centre in signal analysis (in collaboration with researchers of the Technical University Eindhoven), we intend to document "normal" neuroelektrophysiologic development in preterm infants by polysomnography and quantitative analysis of the acquired data, in order to identify potential damaging influences on this development.

During an open observational, non-invasive, non-therapeutic study of a cohort population we will perform weekly polysomnography recordings.

In this first study we will explore electrophysiologic maturation in appropriate for gestational age (AGA) infants and small for gestational infants (SGA) with brain sparing.

Study objective

Goal:

1. Defining normal electophysiologic matarution in premature infants by quantitative analysing techniques;

2. Identifying circumstances that disturb normal electrophysiologic maturation.

Study design

N/A

Intervention

Weekly polysomnography.

Contacts

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Eligibility criteria

Inclusion criteria

Premature infants:

- 1. Gestational Age <30 weeks;
- 2. Cardiorespiratory stabile;
- 3. No major lesions on cerebral ultrasound;
- 4. No abnormalities on neurologic examination.

Two subgoups:

- A. Appropriate for gestational age infants (>p10);
- B. Small for getational age infants (

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

ΝП

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2006
Enrollment:	45
Туре:	Actual

Ethics review

Positive opinion	
Date:	07-07-2006
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	NL718
NTR-old	NTR728
Other	: 001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A