Brainstem auditory evoked response (BAER) measurement in premature infants; effect of bilirubin levels and different nutritional regiments.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27094

Source
Nationaal Trial Register

Brief title
BAER measurement in NICU infants

Health condition

premature infants, brainstem auditory evoked responses, risk factors

Sponsors and support

Primary sponsor: Erasmus medical Center - Sophia Children's Hospital
Source(s) of monetary or material Support: Erasmus medical Center - Sophia Children's Hospital

Intervention

Outcome measures

Primary outcome

BAER parameters.

Secondary outcome

Alteration of BAER parameters in preterm infants over time.

Study description

Background summary

Severe hyperbilirubinemia is known to cause sensorineural hearing loss. An incidence of up to 87% for hearing function disorders diagnosed by abnormal BAER results has been reported18. It is reported that BAER parameters can improve after blood transfusion19-21. However in about 50% of children non reversible changes were found22. Most of these results are from studies in full term neonates. It is suggested that preterm infants are at higher risk of developing hearing disorders as a result of hyperbilirubinemia because the auditory system is affected in an earlier stage of maturation18. In this study we will investigate the effect of bilrubin levels on hearing function in preterm infants by BAER testing. We will investigate changes in auditory function by repeating BEAR testing at 46 weeks postmenstrual age.

Study objective

Higher bilirubin levels (possibly as a results of different nutritional regiments) may alter BAER parameters and cause hearing loss.

Study design

BAER measurement will be obtained within the first 3 weeks after birth and will be repeated at 46 weeks postconceptional age.

Intervention

BAER recording will be conducted at 7 (+/- 2) and 14 (+/- 2) days postnatally and at 46 weeks postconceptional age.

Children will be randomly selected from the following nutritional intervention groups (NIPI-2):

Group A will receive lipids from birth onwards. Group B will receive extra amino acids in combination with lipids from birth onwards. The control group will be fed according to the standard nutrition policy (lipids from day 2 or 3 onwards). Different lipid emulsions will be

compared.

Contacts

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Eligibility criteria

Inclusion criteria

1. Inborn;

2. Gestational weight less than 1500g.

Exclusion criteria

1. Congenital anomalies;

2. Metabolic disease;

3. Endocrine, renal or hepatic disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2009
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	NL1624
NTR-old	NTR1720
Other	METC Erasmus MC : 2008-186
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A