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

Gepubliceerd: 11-03-2009 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27094

Bron
Nationaal Trial Register

Verkorte titel
BAER measurement in NICU infants

Aandoening

premature infants, brainstem auditory evoked responses, risk factors

Ondersteuning

Primaire sponsor: Erasmus medical Center - Sophia Children's Hospital
Overige ondersteuning: Erasmus medical Center - Sophia Children's Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

BAER parameters.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Inborn;

2. Gestational weight less than 1500g.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Congenital anomalies;

2. Metabolic disease;

3. Endocrine, renal or hepatic disorder.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1624
NTR-old	NTR1720
Ander register	METC Erasmus MC : 2008-186
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A