Reducing bilirubin induced neurological dysfunction in preterm infants: additional use of the bilirubin:albumin ratio in the treatment of hyperbilirubinemia.

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Neonatal jaundice due to unconjugated hyperbilirubinemia occurs in almost all preterm infants and is potentially neurotoxic. The current treatment modalities (phototherapy and exchange transfusion) are based on total serum bilirubin (TSB) levels,...

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

Samenvatting

ID

NL-OMON26621

Bron
NTR

Verkorte titel
BARTrial

Aandoening

English: Infants premature, preterm infant, hyperbilirubinemia, bilirubin:albumin ratio, albumin. BIND, bilirubin induced neurological dysfunction. Neurodevelopmental outcome. Nederlands: prematuur, prematuriteit, hyperbilirubinemie, bilirubine:albumine ratio, albumine, BIND, bilirubine geinduceerde neurologische dysfunctie. Neurologische ontwikkeling.

Ondersteuning

Primaire sponsor: Neonatology, Beatrix Children's Hospital, UMC Groningen
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Blinded assessment of the participants outcome is performed.
Primary outcome:
1. Neurodevelopmental outcome at the age of 18-24 months using standardised neurological examination;
2. Mental - and psychomotor developmental index scores (MDI and PDI: Dutch version of Bayley scales of infant development II)

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction: Neonatal jaundice due to unconjugated hyperbilirubinemia occurs in almost all preterm infants and is potentially neurotoxic. The current treatment modalities (phototherapy and exchange transfusion) are based on total serum bilirubin (TSB) levels, but are not evidence based.
TSB is an unreliable predictor of bilirubin induced neurological dysfunction (BIND). Because low albumin levels appear tot potentiate BIND, the bilirubin:albumin (B:A) ratio is an interesting additional factor to assess in the management of preterm infants with hyperbilirubinemia.
Research Question: Does the additional use of the B:A ratio together with TSB reduce BIND in comparison to TSB only, in the management of preterm infants with hyperbiliburinemia?
Study design: prospective randomised controlled open label, blinded outcom multicenter cost-effectiveness multicenter study in tertiary neonatal intensive care units in the Netherlands.
Study population: preterm infants < 32wks GA.
Intervention: hyperbilirubinemia is evaluated daily using the B:A ratio together with TSB (studygroup) versus TSB only (control or care-as-usual-group). Treatment guidelines are based on B:A ratio and TSB (whichever comes first) versus only TSB.
Outcome: primairy: Neurodevelopmental outcome at 18-24 months of age (MDI/PDI)
secondairy: bilirubine associated parameters, standard complications of prematurity, Cost-effectiveness.
Other potential outcomes: ABR, lumirubin. free-bilirubin, TcB.

Doel van het onderzoek

Neonatal jaundice due to unconjugated hyperbilirubinemia occurs in almost all preterm infants and is potentially neurotoxic. The current treatment modalities (phototherapy

and exchange transfusion) are based on total serum bilirubin (TSB) levels, but are not evidence based.
TSB is an unreliable predictor of bilirubin induced neurological dysfunction (BIND). Because low albumin levels appear tot potentiate BIND, the bilirubin:albumin (B:A) ratio is an interesting additional factor to assess in the management of preterm infants with hyperbilirubinemia.

Onderzoeksproduct en/of interventie

Studygroup: Hyperbilirubinemia is evaluated daily, in the first 10 days of life using the B:A ratio together with TSB. Treatment guidelines (phototherapy and exchange transfusion limits) are based on B:A ratio and TSB (whichever comes first)
Controlgroup: Hyperbilirubinemia is evaluated daily, in the first 10 days of life using TSB only (care as usual).
versus only TSB. Treatment guidelines (phototherapy and exchange transfusion limits) are based on TSB only.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Preterm infants born at gestational age less than 32 weeks;
2. Admittance in the first 24 hours of life to a neonatal intensive care unit care center in the Netherlands.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Major congenital malformations, clinical syndromes and chromosomal abnormalities that effect neurodevelopmental outcome.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2007
Aantal proefpersonen:	614
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2007
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	NL911
NTR-old	NTR935
Ander register	:
ISRCTN	ISRCTN74465643

Resultaten