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Reducing bilirubin-induced neurological dysfunction in preterm infants: additional use of the Bilirubin:Albumin Ratio in the treatment of hyperbilirubinemia

Submission date
11/04/2007

Recruitment status
No longer recruiting

Registration date
11/04/2007

Overall study status
Completed

Last Edited
12/04/2021

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.neonatologiestudies.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR935

Study information

Scientific Title
Reducing bilirubin-induced neurological dysfunction in preterm infants: additional use of the Bilirubin:Albumin Ratio in the treatment of hyperbilirubinemia

Acronym
BARTrial

Study objectives
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 to potentiate BIND, the Bilirubin:Albumin (B:A) ratio is an interesting additional factor to assess in the management of preterm infants with hyperbilirubinemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Review Committee (METC) of the University Medical Center Groningen (UMCG) reviewed and approved the study protocol on the 9th January 2007 (ref: ABR nr: NL 14811.042.06).

Study design
Randomised active-controlled parallel-group single-blinded multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hyperbilirubinemia, bilirubin induced neurological dysfunction

Interventions
Study group:
Hyperbilirubinemia is evaluated daily, in the first ten 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)

Control group:
Hyperbilirubinemia is evaluated daily, in the first ten days of life using TSB only (care as usual) versus only TSB. Treatment guidelines (phototherapy and exchange transfusion limits) are based on TSB only.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blinded assessment of the participants outcome is performed.

Primary outcome:
1. Neurodevelopmental outcome at the age of 18 to 24 months using standardised neurological examination will be measured from October 2008 till April 2010
2. Mental- and Psychomotor Developmental Index scores (MDI and PDI: Dutch version of Bayley scales of infant development II) will be measured from October 2008 till April 2010

Secondary outcome measures
Secondary outcomes:
1. Peak total serum bilirubin will be measured from April 2007 till January 2008
2. Duration of hyperbilirubinaemia will be measured from April 2007 till January 2008
3. Duration of phototherapy will be measured from April 2007 till January 2008
4. Number of exchange transfusions will be measured from April 2007 till January 2008

Other outcomes are complications of prematurity such as:
1. Mortality will be measured from April 2007 till the end of this study (April 2010)
2. Bronchopulmonary Dysplasia (BPD) will be measured from April 2007 till January 2008
3. Patent Ductus Arteriosus (PDA) will be measured from April 2007 till January 2008
4. Retinopathy of Prematurity (ROP) will be measured from April 2007 till January 2008
5. Necrotising Enterocolitis (NEC) will be measured from April 2007 till January 2008
6. Intraventricular Haemorrhage (IVH) etc., will be measured from April 2007 till January 2008

Other potential outcomes to be evaluated in parts of the study population are:
1. Maturation pattern of serial Auditory Brainstem Responses (ABR) in a part of the study populations that is treated in those Neonatal Intensive Care Units (NICUs) that are able to perform serial ABRs. This will be measured from April 2007 till January 2008

2. Free (unbound) unconjugated bilirubin will be measured in from January 2008 till October 2008
3. Lumirubin will be measured from April 2007 till January 2008
4. CFM (Cerebral Function Monitor) will be measured from April 2007 till January 2008
5. Movement score will be measured from April 2007 till January 2008
6. Transcutane bilirubin measurement will be measured from April 2007 till January 2008

Overall study start date
01/04/2007

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. Preterm infants born at gestational age less than 32 weeks, either sex
2. Admittance in the first 24 hours of life to a neonatal intensive care unit care centre in the Netherlands

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
614

Key exclusion criteria
Major congenital malformations, clinical syndromes and chromosomal abnormalities that affect neurodevelopmental outcome

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Netherlands

Study participating centre

Beatrix Children's Hospital
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (The Netherlands)

Sponsor details
Beatrix Children's Hospital
P.O. Box 30001
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9700 RB

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/azg/nl/english/azg/

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2008		Yes	No
Results article	results	13/06/2014		Yes	No
Results article	hearing loss results	07/05/2013	12/04/2021	Yes	No