Non-invasive screening and diagnosis of neonatal jaundice

No registrations found.

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

Summary

ID

NL-OMON27271

Source
Nationaal Trial Register

Brief title
STARSHIP (Screening and TreAtment to Reduce Severe Hyperbilirubinaemia in Infants in Primary care)

Health condition

Neonatal jaundice; neonatal hyperbilirubinemia; neonatal hyperbilirubinaemia; neonatale geelzucht; neonatale hyperbilirubinemie; neonatale icterus

Sponsors and support

Primary sponsor: Erasmus MC – Sophia Children's Hospital, Rotterdam
Source(s) of monetary or material Support: This study is funded through a Health Care Efficiency Research grant of The Netherlands Organisation for Health Research and Development (ZonMw) and an Erasmus MC Efficiency Research grant.

Intervention

Outcome measures

Primary outcome

1. The proportion of neonates with severe hyperbilirubinaemia. Severe hyperbilirubinaemia is

defined as a total serum bilirubin level above the mean of the phototherapy and the exchange transfusion threshold according to the Dutch total serum bilirubin nomogram.

2. The proportion of neonates admitted to the hospital for hyperbilirubinaemia treatment.

Secondary outcome

- Highest total serum bilirubin level.

- Proportion of neonates having total serum bilirubin quantified at any time point.

- Number of times blood taken for total serum bilirubin quantification before start of phototherapy.

- Number of times transcutaneous bilirubin is quantified and levels of individual measurements.

- Difference in transcutaneous bilirubin measurement at forehead and sternum (at same time point).

- Proportion of neonates receiving phototherapy.

- Duration (hours) of phototherapy (if relevant).

- Proportion of neonates having a total serum bilirubin level above the exchange transfusion threshold.

- Proportion of neonates who actually received an exchange transfusion.

- Proportion of neonates having kernicterus.

- Duration of hospital stay (if relevant).

- Number of transfers between primary care birth centres/hospitals.

- Number of times paediatrician consulted and outcome of consultation.

- Cost-effectiveness of both interventions.

- Experience of parents (based on a questionnaire).

- Experience of attending health care personnel (based on a questionnaire).

Study description

Background summary

Jaundice due to a temporary rise in serum bilirubin levels is a physiological phenomenon in the neonatal period. However, at high levels bilirubin passes the blood-brain barrier and can cause life-long handicaps due to kernicterus. Timely recognition of potentially severe neonatal jaundice is essential, as phototherapy offers a safe and effective treatment. We seek to determine the
(cost-)effectiveness of using transcutaneous bilirubinometry as a non-invasive screening tool for neonatal jaundice in primary care, as well as the (cost-)effectiveness of applying phototherapy in this setting, when indicated, to avoid hospital admission.

Study objective

We hypothesise that among babies admitted to primary care birth centres:

1. Non-invasive screening for neonatal jaundice will (cost-)effectively reduce the incidence of severe hyperbilirubinaemia.

2. Should treatment for hyperbilirubinaemia be indicated, initiation of phototherapy in the primary care birth centre will (cost-)effectively reduce the need for hospital admission.

Study design

The primary outcomes and the secondary outcomes will be defined within the first 14 days of life of the neonate. The only exception is the proportion of neonates having kernicterus, since kernicterus is usually not diagnosed within the first 14 days of life. The proportion of neonates having kernicterus will be defined within the first year of life.

Intervention

1. Repeated transcutaneous bilirubinometry as a screening tool for jaundice and secondary selective measurement of total serum bilirubin.

2. Application of phototherapy in primary care birth centres if hyperbilirubinaemia is present.

Control:

1. Visual assessment of jaundice and selective measurement of total serum bilirubin.

2. Phototherapy in the hospital.

Contacts

Public
Erasmus MC
B.A.M. Geest, van der
Rotterdam
The Netherlands
010-7030229
Scientific
Erasmus MC
B.A.M. Geest, van der
Rotterdam
The Netherlands
010-7030229

Eligibility criteria

Inclusion criteria

Neonates are eligible if:

- They were born after 35 completed weeks of gestation.

- They are admitted in a participating primary care birth centre during the study period within the first week of life.

- They are expected to remain admitted for at least two days.

- Signed informed consent is available from parent(s).

Exclusion criteria

Neonates are not eligible if:

- They previously received phototherapy.

- They have large congenital anomalies at the sternum or forehead.

- Parents do not have sufficient understanding of the Dutch language to be able to comprehend the patient information sheet.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-07-2018
Enrollment:	5500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55558
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6997
NTR-old	NTR7187
CCMO	NL62027.078.17
OMON	NL-OMON55558

Study results