A parallel evaluation of three novel screening methods for hyperbilirubinaemia in newborns cared for at home (BEAT Jaundice @home): an observational, prospective multicentre study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23353

Source
Nationaal Trial Register

Brief title
BEAT Jaundice @home

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam – Sophia Children's Hospital and University Medical Center Groningen - Beatrix Children's Hospital
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary objective is to assess whether universal TcB screening can increase the detection of neonates with hyperbilirubinaemia necessitating treatment compared to using only visual inspection, and at the same time decrease the number of heel pricks performed to quantify total bilirubin in blood. As such, there are two primary endpoints assessed at each time point for each neonate:

(1) LBB above the treatment threshold

(2) the need for a heel prick to determine LBB.

Secondary outcome

1. Diagnostic properties and effectiveness of TcB

1.1 Added value of TcB compared to only visual inspection in picking up neonates with hyperbilirubinemia requiring treatment, while reducing the need for heel pricks to quantify bilirubin in blood

1.2 TcB versus LBB

2. Diagnostic properties and effectiveness of Picterus®

2.1 Added value of Picterus® app compared to only visual inspection in picking up neonates with hyperbilirubinemia requiring treatment, while reducing the need for heel pricks to quantify bilirubin in blood

2.2 Picterus® app versus LBB

2.3 Picterus® app versus TcB

2.4 Added value of combining TcB and Picterus®

3. Diagnostic properties and effecteviness of Bilistick®

3.1 Bilistick® versus LBB

3.2 Difference in time-to-test result between LBB and Bilistick®

4. Proportion of neonates receiving phototherapy

5. Proportion of neonates having a LBB level above the phototherapy threshold

6. Proportion of neonates having a LBB level above the exchange transfusion threshold

7. Proportion of neonates who actually received an exchange transfusion

8. Potential cost-effectiveness of implementation of the novel methods in daily practice

9. User-convenience of TcB, Picterus® and Bilistick®

10. Experience of parents

Study description

Background summary

Severely elevated bilirubin levels can place a neonate at risk for permanent brain damage, acute bilirubin encephalopathy or – on the long term – kern icterus spectrum disorder. Therefore, early diagnosis of severe neonatal hyperbilirubinemia (SNH) is essential to prevent these deleterious sequelae. Although known to be unreliable, visual inspection followed by selective laboratory-based bilirubin (LBB) quantification remains the current standard to prevent SNH in neonates cared for at home in the Netherlands. We aim to evaluate the effectiveness, diagnostic properties and cost-effectiveness of three novel approaches for screening and diagnosing neonatal hyperbilirubinemia in the home setting: transcutaneous bilirubinometer (TcB; Draeger JM-105), a smartphone app (Picterus®) and a point-of-care device for quantifying total bilirubin (Bilistick®).

Study objective

We hypothesise that among well neonates cared for at home during day 2-8 of life:
1. Universal TcB screening will improve recognition of neonates having hyperbilirubinaemia requiring treatment compared to visual inspection, while decreasing the need for heel pricks to quantify bilirubin in blood in case of suspected hyperbilirubinaemia.
2. The Picterus® app correlates well with TcB and laboratory-based bilirubin (LBB)levels and use of the Picterus® app will improve recognition of neonates having hyperbilirubinaemia necessitating treatment compared to visual inspection, while decreasing the need for heel pricks to quantify LBB.
3. In neonates requiring bilirubin quantification in blood, Bilistick® will have similar total bilirubin readings compared to LBB quantification, while reducing the time-to-test result to determine total bilirubin in blood.

Study design

The primary outcomes and the secondary outcomes will be defined within the first 14 days of life of the neonate.

Intervention

1. Transcutaneous bilirubinometer (TcB; Draeger JM-105): a non-invasive method for estimating total bilirubin in blood
2. Picterus® app: a smartphone app which screens for neonatal jaundice using a photograph taken by a smartphone
3. Bilistick®: a commercially available point-of-care test for total bilirubin in whole blood

Contacts

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Eligibility criteria

Inclusion criteria

Neonates are considered eligible for inclusion if they:
- are born at a gestational age of at least 35 weeks
- are cared for at home during day 2-8 of life
- have their first midwife visit at home prior to day 6

Exclusion criteria

Neonates are not considered eligible if they:
- previously received phototherapy
- Parents who have no sufficient understanding of the Dutch language to be able to understand the patient information sheet

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-06-2021
Enrollment:	2310
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	22-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55110
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9545
CCMO	NL74483.078.20
OMON	NL-OMON55110

Study results

Summary results
N/A