Better assessment of neonatal jaundice at home (BEAT jaundice @ home)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON55110

Source
ToetsingOnline

Brief title
BEAT jaundice @ home

Condition

- Hepatic and hepatobiliary disorders
- Neonatal and perinatal conditions

Synonym
jaundice, Neonatal hyperbilirubinaemia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: home, neonatal jaundice, screening and diagnosis

Outcome measures

Primary outcome

The primary outcome of the study is the added value of universal TcB screening compared to only visual inspection to detect neonatal hyperbilirubinaemia requiring treatment, while decreasing the need for heel pricks to quantify total bilirubin in blood.

As such, the study has two primary endpoints, assessed at each time point for each newborn in the study: 1. LBB above the treatment threshold; 2. Need for a heelprick (to determine LBB).

Secondary outcome

• Diagnostic properties of Bilistick®.

• Difference in time-to-test result between LBB and Bilistick® (in minutes).

• Difference in blood volume between LBB and Bilistick® (in µl).

• Diagnostic properties of Picterus® app vs. TcB and LBB.

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

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

• Proportion of neonates receiving phototherapy.

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

• Proportion of neonates having a LBB level above the exchange transfusion

threshold.

• Proportion of neonates who actually received an exchange transfusion.

Study description

Background summary

Neonatal jaundice occurs in up to 85% of term newborn infants. It is caused by elevated circulating bilirubin levels that peak in the first week of life. However, when bilirubin levels are very high and left untreated, bilirubin may pass the blood-brain barrier and cause permanent brain damage (also called kernicterus spectrum disorder; KSD). Timely recognition and treatment of severe neonatal hyperbilirubinaemia is thus essential. In current practice, visual inspection is used as a first-line screening tool to assess jaundice. However, visual inspection is known to be unreliable and reliance on visual inspection to detect neonatal jaundice can cause significant diagnostic and therapeutic delay. Accordingly, bilirubin levels rise to dangerous levels sufficiently severe to cause imminent KSD in a significant number of neonates each year. Novel screening and diagnostic methods for early detection of potentially severe neonatal hyperbilirubinaemia are urgently needed in order to prevent KSD.

Study objective

The primary objective of the study is to assess the proportion of neonates with hyperbilirubinaemia necessitating treatment that is detected using universal TcB screening compared to using only visual inspection, while decreasing the number of heel pricks to quantify total bilirubin in blood (per neonate).

Study design

Prospective observational study.

Study burden and risks

In this study, we will investigate three novel approaches to recognise and diagnose neonatal hyperbilirubinaemia:
1. TcB screening
TcB measurement is safe and has been shown to be effective in reducing the incidence of severe hyperbilirubinaemia in other settings. TcB quantification is a non-invasive and painless procedure which involves holding the device to the neonate*s skin for a few seconds.
2. Picterus mHealth app

Picterus® is a mobile application that uses a photograph of the sternum with a colour calibration card to estimate total bilirubin levels. This application is installed on a smartphone provided by the study team.
3. Bilistick®
Bilistick® is a POC instrument to quantify bilirubin in one drop of whole blood drawn from a heel prick. Bilistick® will only be used if LBB quantification is needed, based on visual inspection and/or TcB screening. Accordingly, participating neonates will not need an extra heel prick for Bilistick® assessment.

As neonates are the only group suffering from neonatal hyperbilirubinaemia, these three novel approaches can only be investigated in neonates/in the neonatal phase.
In conclusion, we consider the risks low, whereas the novel approaches have potential to offer major benefits to neonates.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

• Born at a gestational age of at least 35 weeks.
• Cared for at home between day 2 and 8 of life.
• Having a first midwife visit at home prior to day 6.
• Written informed consent according to the national guidelines of both parents or legal representatives. Given the low risks of participating in the study, referred consent of the second parent is allowed as well.

Exclusion criteria

• The neonate previously received phototherapy (as reliability of TcB measurement is reduced in neonates who have received phototherapy).
• The neonate has parents who do not have sufficient understanding of the Dutch language to be able to comprehend the patient information sheet.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-07-2021
Enrollment:	2310
Type:	Actual

Ethics review

Approved WMO Date:	21-05-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-10-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23353
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74483.078.20
OMON	NL-OMON23353