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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23353

Bron
Nationaal Trial Register

Verkorte titel
BEAT Jaundice @home

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam – Sophia Children's Hospital and University Medical Center Groningen - Beatrix Children's Hospital
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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®).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-06-2021
Aantal proefpersonen:	2310
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	22-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55110
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A