Optical spectroscopy for monitoring bilirubin and hemoglobin levels in neonates

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Ethical review	Approved WMO
Status	Pending
Health condition type	Haematological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON33261

Source
ToetsingOnline

Brief title
Optical monitoring of neonates

Condition

- Haematological disorders NEC
- Metabolism disorders NEC
- Neonatal and perinatal conditions

Synonym
anemia, jaundice

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: NWO-STW VIDI vernieuwingsimpuls

Intervention

Keyword: bilirubin, hemoglobin, neonates, spectroscopy

Outcome measures

Primary outcome

The bilirubin and hemoglobin concentrations in the skin and the blood vessels

in the skin.

Secondary outcome

Influence of age, influence of measurement site, influence of skin thickness,

influence of skin type.

Study description

Background summary

Neonatal bilirubin and hemoglobin blood levels are measured by laboratory blood analysis, after invasive blood sampling. This is an invasive and time consuming procedure, causing a relatively large time interval between the moment treatment is needed and the time of blood sampling. Complications as a result of invasive blood sampling (pain, inflammation, cutaneous calcifications) are often observed in preterm neonates, who require close monitoring of body function to prevent hyperbilirubinemia, anemia and hypoxia. Neonates at the intensive care require up to 5 heel sticks a day.
Optical spectroscopy possibly offers an alternative for measuring bilirubin and hemoglobin levels. In comparison to blood sampling, optical spectroscopy is a non-invasive technique and offers the possibility of monitoring (real-time measuring) blood levels.

Study objective

In this study, we will investigate the use of optical spectroscopy in determining neonatal bilirubin and hemoglobin blood levels. The outcome and accuracy of the optical spectroscopy measurements will be compared to the outcome of laboratory blood analysis.

Results will be used to validate and further develop the technique.

Study design

In this pilot study, we will measure neonates at the neonatology department at the AMC to determine the main factors of influence on the determination of bilirubin and hemoglobin levels with optical spectroscopy. Currently, it is not clear which factors are of influence on this determination. We expect influence of: skin type, skin thickness, measurement site on the body, gestational age and age after birth. We will perform a spectroscopy measurement on a patient each time an invasive blood analysis is carried out, for other reasons than this study. The measurements with optical spectroscopy will be compared to the bilirubin and hemoglobin levels from invasive blood analysis. Therefore it is important to perform the measurements directly before, or after blood sampling. In addition to the spectroscopy measurements, we perform a skinfold measurement at the upper arm to determine skin thickness.

Study burden and risks

There are no burdens and risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Known bilirubin and/or hemoglobin blood levels from invasive blood analysis (blood drawn for other reasons than this study).

Exclusion criteria

Unknown bilirubin and hemoglobin levels.
Affections that hamper the practical feasibility of the measurements (skin irritations etc.).
Observable resistance or discomfort during the measurements for the patient (e.g. increased stress levels).
The latter two criteria will be judged by the treating physician and compared to the guidelines of the behavioural code of the Nederlandse Vereniging voor Kindergeneeskunde.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL27442.018.09