Evaluation of a non-invasive dynamic light scattering sensor for the measurement of heart rate in neonates.

Published: 21-03-2017
Last updated: 14-04-2024

Our primary objective is to correlate the measured heart rates between ECG measurements and the Elfi-Tech dynamic light scattering sensor.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45284

Source
ToetsingOnline

Brief title
NEO-DLS

Condition

- Other condition
- Body temperature conditions
- Hepatobiliary neoplasms malignant and unspecified

Synonym
premature birth, Prematurity

Health condition

prematuriteit

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dynamic light scattering, Electrocardiogram, Heart rate, Neonates

Outcome measures

Primary outcome

The main study endpoint is the correlation of the detection of heart rate in

beats per minute between ECG and the Elfi-Tech DLS sensor.

Secondary outcome

The correlation between flow measured with the Elfi-Tech DLS and Pulse Index

(PI) from the pulse oximeter

Peak detection and beat to beat analysis for the detection of measurement

errors and signal disturbances.

Determination of optimal measurement site.

Assessment of measurement quality in patient groups with impaired peripheral

perfusion; sepsis and therapeutic hypothermia.

Heart rate variability measurements with ECG, pulse oximetry and the Elfi-Tech

DLS sensor and their correlation.

Study description

Background summary

One of the most important vital parameters that are measured in neonates is heart rate. This is most commonly detected using electrocardiography (ECG). Prematurely born infants in particular are known for frequent episodes of

bradycardia (slow heart rate) that require adequate detection because they indicate low cardiac output. To date electrocardiography is the gold standard for non-invasive heart rate detection. Pulse oximetry is also common clinical practice for non-invasive heart rate monitoring, as it provides the blood oxygen saturation as well. Both ECG and pulse oximetry have a very small signal amplitude in neonates, which makes it difficult to detect and even harder to properly quantify the signal. Another major issue is signal distortion by movement of the neonate and in the case of ECG also electromagnetic interference. An important remark concerning the measurement of vital signs in (premature) neonates is their very small size, allowing only a limited number of sensors for patient monitoring. The company Elfi-Tech has recently developed a new dynamic light scattering sensor which is able to measure heart rate through the assessment of skin blood flow with a single sensor. This new measuring technique is less susceptible to movements of the neonate or to electromagnetic interference.

Study objective

Our primary objective is to correlate the measured heart rates between ECG measurements and the Elfi-Tech dynamic light scattering sensor.

Study design

This study is a prospective observational study. After informed consent is obtained we will measure for 75 minutes with the Elfi-Tech DLS sensor on 5 different sites. This measurement is compared to heart rate measurements obtained by ECG monitoring at the same time. Also a secondary pulse oximeter will be attached

Study burden and risks

We will perform non-invasive measurements for the duration of 75 minutes, the burden associated with participation is therefore minimal.
When the sensor is placed it does not come into direct contact with the skin, but is attached to a certified biocompatible double-sided adhesive which functions as a barrier. These double-sided adhesives have often been used in neonatal studies and are known to have no consequences for the premature skin.

This DLS sensor contains a divergent class 1 laser source that is safe from any distance. This means that even when directly viewing this laser with the naked eye the maximum permissible exposure cannot be exceeded, making it harmless to the eye. However, considering the frailty of the neonates in which this study is performed the sensors will be handled with caution and exposing the eyes of the patients to the laser will be avoided at all times. The rationale is that even though a class 1 is deemed safe in the general population, the neonatal retina and the premature retina in particular, is more sensitive. In addition,

information on the consequences of exposing the eye of a neonate to a class 1 laser is lacking.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Aged 26 weeks of gestation or older.
Monitored by electrocardiogram in the Neonatal Intensive Care Unit of the Sophia Children*s Hospital.
Written informed consent.

Exclusion criteria

Absence of written informed consent
A gestational age of < 26 weeks
Skin disorder (including frailty of the skin) for which the double sided skin adhesive is contraindicated.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2017
Enrollment:	46
Type:	Actual

Medical products/devices used

Generic name:	Dynamic light scattering sensor
Registration:	No

Ethics review

Approved WMO Date:	22-03-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-11-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL59350.078.16