Pilot study ENEMO-Contactless Core Temperature Monitoring for the NICU

Published: 31-10-2012
Last updated: 26-04-2024

The primary objective of this study is to validate the use of a zero-heat flow temperature sensor for the measurement of core body temperature in the NICU by comparing it with 2 other modalities for core temperature measurement.

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

Summary

ID

NL-OMON37059

Source
ToetsingOnline

Brief title
Pilot study Core temperature NICU

Condition

- Other condition

Synonym
n.v.t. het betreft temperatuur bewaking zonder indicatie van aandoeningen

Health condition

n.v.t. het betreft temperatuur bewaking zonder indicatie van aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contactless, Neonatal monitoring, NICU, Temperature

Outcome measures

Primary outcome

The primary study parameter is to validate the temperature difference between the ZHF sensor and the temperature of the feedingtube. The difference has to be less than 0.2 degree.

Secondary outcome

1. Observing the function of the InnerSense feeding tube over time with respect to feeding periods, feeding quantity and feeding method.

2. Observing the change of temperature per neonate in context of the procedures performed and the health condition of the neonate.

3. What is the effect of the location of the ZHF sensors on the accuracy of temperature values measured?

Study description

Background summary

The aim is to reduce pain and stress for premature infants at the NICU.
Although core body temperature is a key physiological parameter in the NICU, current methods of measurements still use adhesive skin probes , that can

affect the comfort of neonates.

The purpose of this clinical investigation is the evaluation of non invasive sensors (temperature sensor inside the diaper and Zero Heat Flow sensor) in comparison with standard methods of measuring core temperature. The zero heat flow (ZHF) technology itself is a novel contactless technology that replaces uncomfortable probes for core temperature measurement.

The measurements from the ZHF sensors will be compared with the clinical method that is currently applied: a temperature sensor embedded in the diaper. Since this method not necessarily displays the core temperature at all times we include temperature measurements from an Innersense feeding tube. This is a CE approved commercially available feeding tube for newborn infants that is equipped with a temperature sensor to obtain the oesophageal temperature that equals the core temperature. For this study this Innersense tube replaces the feeding tube that is used presently.

Study objective

The primary objective of this study is to validate the use of a zero-heat flow temperature sensor for the measurement of core body temperature in the NICU by comparing it with 2 other modalities for core temperature measurement.

Study design

The plan is to perform a 8h measurement on each neonate (8h hour is the approximate duration, exact duration will be decided case by case to avoid interference with the planned workflow). 2 groups of neonates will be recruited: neonates under 32 weeks of age and neonates above 32 weeks of age. The first 2 neonates will be recruited in the medium care unit, among neonates who are using a feeding tube. All neonates recruited will be using a feeding tube.

As the weight range of neonates is between 500g-5kg and age between 24-42 weeks, we expect to see differences in movement behavior between the neonates. Therefore we would like to perform measurements on children with different weights and ages. Measurements will be started on the most stable (thus older and heavier) neonates. It is likely that during the first measurements unforeseen problems will arise causing a necessary restart of the system. For the older neonates this is not a problem or added burden. However the very small neonates are better left undisturbed; therefore they will form the last category that will be tested. Data processing will start while measurements are being conducted. If it is deemed relevant for the study and safe for the neonates also the more critical (young and low weight) neonates will be included in this study.

Study burden and risks

The risks of the study have been analyzed. Potential risks have been mitigated to an acceptable level. A risk analysis document is included in the METC submission.

Contacts

Public
Philips Research

High Tech Campus 34
Eindhoven 5656AE
NL
Scientific
Philips Research

High Tech Campus 34
Eindhoven 5656AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Subjects will include neonates in the NICU and the medium care unit. The decision to include a neonate in the study will be made by Prof. dr. S. Bambang Oetomo in consultation with other clinicians at the MMC NICU. Subjects are premature infants born after a gestation of less than 34 weeks.

Exclusion criteria

Neonates who are unstable or suffering from complications (major respiratory problems, low blood pressure, or severe infections) will be excluded from the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2012
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL41718.015.12