Peri-operative, unobtrusive core temperature measurement

Gepubliceerd: 20-07-2016 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON26681

Bron
Nationaal Trial Register

Aandoening

Unobtrusive core temperature measurement during surgery

Ondersteuning

Primaire sponsor: Philips Research
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The comparison of the results from all the sensors

Toelichting onderzoek

Achtergrond van het onderzoek

Title: Peri-operative, unobtrusive core temperature measurement - clinical pilot trial

Sponsor: Philips Electronics Nederland B.V. acting through Philips Research represented by Henk van Houten

Primary objective

Compare the performances of unobtrusive prototype sensors to CE-marked oesophageal and/or rectal reference sensor (Covedien Mon-a- Therm, General Purpose Temperature Probe 400TM) for core body temperature in patients undergoing surgery in which core temperature management is part of standard procedure (Applying the covedien oesophageal and/or rectal sensor is part of this standard procedure).

The study focus is on stability and accuracy of the prototype sensors in conjunction with different locations. This is one of the preliminary steps to come to a low-cost and easy-to- use core body temperature measurement system for in-hospital use.

Secondary objective(s)

(1) To observe the effect of surgery duration and type on the drop in core temperature.

(2) Observe the comfort and ease of use of the prototype sensor

Devices to be used

1. A commercially available temperature measurement system manufactured by the company Covidien (Mon-a- Therm, General Purpose Temperature Probe 400TM, CE-marked) is applied for referencing.This device is, as part of the standard procedure, placed in the oesophagus and/or rectal.

a. This system is attached to the standard GE anesthesia monitoring system (CE-marked) via the official temperature input on the monitor.
b. The data from the GE anesthesia monitoring system are stored in the electronic patient data managent system every minute. At the end of each test this data is retreived from this system.

2. A commercial available ear temperature device manufactured by the company Braun (CE-marked) is applied for referencing during the pre-operative phase.

3. The components of the newly developed Philips system are:
a. Passive sensors which comprises a sensor spot consisting of temperature sensors surrounded by silicon. These sensors are attached to the volunteers skin by the use of an adhesive designed for medical use.

b. A data recorder (so called “The Squirrel” (CE-marked with cables. Declaration of Conformity according to EMC directive 2004/108/EC) logs and stores the electricial signals from the sensors.

Participating parties and their roles

The study will be conducted at the Sint Elisabeth Hospital in Tilburg. The principal investigator at the site of the investigation, GJ. Noordergraaf, will be responsible for patient inclusion, but will only supervise this. Philips will provide Igor Paulussen (MPA and research scientist) and Eefje Arts-Hornix (research engineer) at institution’s site to support the execution of the research plan, including providing relevant training of the personnel at the institution’s site (e.g. for use of data logger), and data recording, storage, and transfer to Philips. From Philips, Calina Ciuhu-Pijlman(project leader), and a student will also be at the sponsor’s site for the execution of the research plan, including data analysis and interpretation. From the investigational site, Gerrit Jan Noordergraaf is appointed for blinding of privacy-sensitive information.

Subjects

We wish to include 40 adult (≥18 years) patients planned to undergo surgery with temperature management as standard part of the procedure. These patients are routinely equipped with an oesophageal and/or rectal temperature sensor. Exclusion criteria are: neuro-trauma, pregnancy, obesity (BMI>40), and a significant language barrier that prevents the patient from understanding the Informed Consent.

Investigation design

Observational study, compliant with ISO 14155.

Investigation
procedures

Patients will undergo planned surgery. This observational pilot study, compliant with ISO 14155, will not change anything in relation to their care except for the addition of extra non-invasive prototype temperature sensors (placed at e.g. neck, forehead, behind the ear). Temperature measurements from the reference sensors and the prototype temperature sensors are collected every minute during the surgery. The device connected to the prototype temperature sensors is not monitoring the patient in the regulatory meaning of the word, but only records temperature values without displaying them. Data recording times depend on the duration of surgery and are limited by the battery life of the data acquisition device. The administration of medication as well as other potentially important events will be reported on the case report form.

Milestones

20-06- 2016 Start of the study

01-07- 2016 Inclusion of first patient

01-09- 2016 Inclusion of first 10 patients

15-11- 2017 Inclusion of all 40 patients

30-12- 2017 Analysis and presentation of the data of all patients

30-01- 2018 End of the study

Onderzoeksopzet

Every minute pre-operative and during surgery

Onderzoeksproduct en/of interventie

Patients who are undergoing planned surgery in which core temperature management is part of standard procedure (esophageal and/or rectal), will receive extra prototype core temp sensors These sensors are applied in the holding area one hour before the operation starts. Depending on the sensors and it’s shape it can be applied e.g. behind the ear, on the

forehead and/or in the neck.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-≥18 years patients planned to undergo surgery with temperature management as standard part of the procedure. These patients are routinely equipped with an (oesophageal and/or rectal) temperature sensor.

- patients where the expected surgery duration is more than 2 hours.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- neuro-trauma

- pregnancy

- prone position during surgery or intensive care

- obesity (BMI>40)

- significant language barrier that prevents the patient from understanding the Informed Consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	06-07-2016
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-07-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43540
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5821
NTR-old	NTR5976
CCMO	NL56401.028.16
OMON	NL-OMON43540

Resultaten