Peri-operative unobtrusive core temperature measurement - clinical pilot trial

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Compare the performance of an unobtrusive new medical device with a CE-marked esophageal and/or rectal reference sensor (Covedien Mon-a-Therm, General Purpose Temperature Probe 400TM) for core body temperature in patients undergoing surgery in which...

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

Summary

ID

NL-OMON43540

Source
ToetsingOnline

Brief title
CoreTemp@OR

Condition

- Other condition

Synonym
Core temperature

Health condition

chirurgische en medische verrichtingen

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: Core Temperature, Surgery

Outcome measures

Primary outcome

Core temp values

Secondary outcome

Not applicable

Study description

Background summary

Core temperature is the best single indicator of thermal status in humans. Currently obtrusive probes are used to measure it during operations. These include esophageal, rectal or bladder probes, which can be obtrusive to patients, cause irritation or bleeding, and create a risk of infection. Our goal is develop a new medical device (disposable single sensor) that is reliable, comfortable and non-invasive and which provides a continuous measurement to follow the patient for the all duration of hospital stay and to replace the invasive probes (rectal, esophageal and bladder) overcoming the related problems.

Study objective

Compare the performance of an unobtrusive new medical device with a CE-marked esophageal 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 esophageal and/or rectal sensor is part of this standard procedure). The study focus is on stability and accuracy. 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.

Study design

Observational study

Study burden and risks

Not applicable

Contacts

Public
Philips Research

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Scientific
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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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. (In ETZ bladder sensors are not routinely used).

Exclusion criteria

Exclusion criteria are: neuro-trauma, known pregnancy, prone position during surgery, obesity (BMI>40), and a significant language barrier that prevents the patient from understanding the Informed Consent or answering the questionnaire.

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):	11-07-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Temperature sensor
Registration:	No

Ethics review

Approved WMO

Date:	15-06-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO

Date:	28-11-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26681
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56401.028.16
OMON	NL-OMON26681

Study results

Date completed:	24-11-2017
Actual enrolment:	29

Summary results
Trial ended prematurely