Comparative evaluation of body temperature measurement and invasive temperature monitoring in an intensive care setting

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This study*s research objective is to investigate the validity of BT measurement through skin temperature and skin heat flux measurement by the Corsano CardioWatch 287-2 against invasive rectal body temperature monitoring devices in a clinical...

Ethical review	Approved WMO
Status	Pending
Health condition type	Body temperature conditions
Study type	Observational invasive

Summary

ID

NL-OMON57407

Source
ToetsingOnline

Brief title
ICU-TEMP Study

Condition

- Body temperature conditions

Synonym
Fever, pyrexia

Research involving
Human

Sponsors and support

Primary sponsor: Corsano Health B.V.

Source(s) of monetary or material Support: Corsano Health B.V.

Intervention

Keyword: Body Temperature, Continuous rectal temperature sensor, Intensive Care Unit, Wristband

Outcome measures

Primary outcome

The main objective is to validate the clinical accuracy of BT spot measurements by the Corsano CardioWatch 287-2 according to ISO 80601-2-56;2017+A1;2018

Secondary outcome

The secondary objective is to compare continuous CBT measurements by the Corsano CardioWatch 287-2 with measurements from a clinically conventional, continuous rectal temperature sensor. Additionally, bias and limits of agreement for CardioWatch 287-2 will be calculated in comparison to the rectal temperature probe measurements.

As a third goal, simultaneously available thermometer readings of clinical thermometers, for example tympanic temperature readings, Radius-T temperature sensor readings and rectal temperature probe readings, will be compared with each other to assess the difference in respect to each other.

The fourth goal of this study will be to record and evaluate adverse events from the wearable CBT sensor (e.g., rash).

Study description

Background summary

Fever is one of the most common clinical symptoms. So far, clinically established methods to monitor body temperature (BT) are either invasive and expensive (blood, bladder or rectal catheter) and/or non-continuous (tympanic temperature measurements). A continuous and scalable BT monitoring solution is missing. The Corsano CardioWatch 287-2 is a wristband intended to monitor multiple vital signs, including BT. It does so by continuously measuring the wrist*s skin temperature and corresponding heat flux, from which it predicts the BT. These BT predictions are performed in real-time by a machine learning algorithm on the wearable itself. The sensor system was shown to have good correlation with tympanic temperature measurements in an acute stroke clinical setting. However, a clinicial validation study in which the sensor is integrated in the Corsano CardioWatch 287-2 is lacking.

Study objective

This study*s research objective is to investigate the validity of BT measurement through skin temperature and skin heat flux measurement by the Corsano CardioWatch 287-2 against invasive rectal body temperature monitoring devices in a clinical setting.

Study design

This is a single-center validation study in the Renier de Graaf Gasthuis. Temperature readings from wearable BT sensors, tympanic temperature, Radius-T temperature sensor and rectal temperature will be collected. Study participants will be monitored with a maximum of 24 hours. Other than the wearable BT sensor, the Radius-T temperature sensor and the rectal thermometer no additional interventions will take place due to the study. Temperature monitoring of patients will be performed according to hospitals routine care and will not be affected by the study. Patients may receive additional treatment to ensure best care.

Study burden and risks

The study involves wearing the Corsano CardioWatch 287-2 during the stay in the Intensive Care Unit or recovery room. This does not entail significant risk for the patient. Wearing several sensors for a time might be slightly uncomfortable. Skin irritation may occur. Placement of the rectal probe can cause discomfort, irritation or rectal abrasion. However, the burden and time effort for included participants is judged as low. Participation is voluntary. Relevant incidental findings are not expected. In the future, the patient

population involved in this trial will benefit from a continuous monitoring device that is considerably less intrusive than conventional monitoring devices. This will facilitate long-term continuous intra- and extramural monitoring of vital signs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients
- >= 18 years old;
- Able to provide consent
- Administered at the ICU or recovery room of the Reinier de Graaf hospital.

Exclusion criteria

- Unable to wear the Corsano CardioWatch 287 or Radius-T temperature sensor due to reasons such as allergic reactions, wounds, amputations etc.;
- Unable to receive rectal temperature monitoring;
- Thermoregulatory problems or diseases;
- Hyperthermia;
- Known allergy to plastics / latex;
- Patient not willing to sign informed consent;
- Significant mental or cognitive impairment.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	Corsano CardioWatch 287-2
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-04-2025
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL86414.058.24