Validation of fever thermometers in a clinical setting

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Primary Objective: Examine the accuracy of generated temperature values with three devices (Exergen, Braun and Genius) in concordance to rectal temperature in patients admitted to the Emergency Department (ED). Secondary Objective: Recommend the...

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

Summary

ID

NL-OMON51535

Source
ToetsingOnline

Brief title
Fever-study

Condition

- Other condition

Synonym
febrile temperature, fever

Health condition

temperatuur

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: devices, fever, method-comparison

Outcome measures

Primary outcome

Primary: Measuring the accuracy of generated temperature values using Exergen TAT-5000 (temporal artery), Genius 3 (tympanic membrane), the Braun ThermoScan 6520 (tympanic membrane), in concordance to Thermoval Rapid (rectal).

Secondary outcome

Demographic characteristics * age, sex, body mass and stature - will be retrieved from the participant by the student researcher, and used as confounder in the analysis

Study description

Background summary

Fever (temperature of the human body core exceeding 38°C) is a common symptom of several medical conditions and in particular infectious diseases (Kluger et al., 1998). The temperature measurement device should be reliable and easy to use.
Reliable methods are rectal and oesophageal measurement methods, but these are not user nor patient friendly. Consequently, other over-the-counter methods are dominating the market and sales increase during influenza outbreaks (Villamarín et al., 2013). Commonly used non-invasive methods include infrared measures on the forehead or in the ear. Although various studies showed that these devices are accurate when calibrated, the temperature measured in humans is often not corresponding to a golden standard such as rectal and oesophageal thermometers that give consistent readings in exercise studies (Daanen, 2006; Kistemaker et al., 2006; Teunissen et al., 2011) and clinical studies (e.g., (Lefrant et al.,

2003)). As a consequence, an inaccurate measurement could mean that any necessary policy to be started is delayed or not started at all, with all the associated problems.
Therefore, the Faculty of Behavioral and Movement Sciences of VU Amsterdam was approached by clinical physicists from three academic hospitals (Amsterdam, Groningen and Leiden) to investigate the three most common used systems. The first study was conducted under controlled lab conditions in which 1) the systems were calibrated and 2) body core temperature in healthy subjects was increased to values of 38°C (Koning, 2021).

The pilot study gives an idea of possible shortcomings of the systems used in academic hospitals, but the proof of the pudding is in clinical measurements. This second study will be a method comparison study as described hereafter

Study objective

Primary Objective: Examine the accuracy of generated temperature values with three devices (Exergen, Braun and Genius) in concordance to rectal temperature in patients admitted to the Emergency Department (ED).
Secondary Objective: Recommend the academic hospital on which device is best to use.

Study design

A method comparison study will be conducted, using four different temperature measuring devices (Braun, Exergen, Genius and Thermoval Rapid

Study burden and risks

There are no risks foreseen in participation since patients in critical conditions are excluded

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

Participants must meet the following criteria:
* 18 years or older
* According to the applied triage protocol, measurement of temperature will already be a necessary test given the entry-complaints, assessed by emergency department nursing staff.
* The attending physician may request temperature measurement for diagnostic reasons.
* Proficiency in Dutch or English language, or accompanied by an (in)formal caregiver proficient in these languages.

Exclusion criteria

Participants who meets any of the following criteria will be excluded:
* Inability to give consent, due to life-threatening situations or reduced consciousness,
* Incapacitated patients, i.e. patients who do not understand the information about their illness, treatment; cannot decide for themselves or do not understand the consequences of a decision,
* pregnancy
* congenital or acquired anomaly of the external auditory meatus
* diseases of the ear.
* participants with haemorrhoids to avoid discomfort and possible bleeding during rectal measurements.

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):	19-05-2022
Enrollment:	225
Type:	Actual

Medical products/devices used

Generic name:	fever device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-05-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL79962.018.22