Feasibility study to measure Thermal Indicator Dilution Curves with a photonic sensor in human volunteers

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Proof of Principle: to assess feasibility to measure; (1) a reproducible 1st thermal IDC, (2) at least 1 recirculation IDC using the FBG photonic sensor both peripheral and nasal. - to compare the acquired Stroke Volume (SV) and Cardiac Output (CO)...

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

Summary

ID

NL-OMON56328

Source
ToetsingOnline

Brief title
Photonic registration of Thermal Indicator Dilution Curves (IDC) in man.

Condition

- Other condition
- Heart failures
- Cardiac therapeutic procedures

Synonym
Cardiac Output, Circulating Blood Volume

Health condition

cardiovasculaire monitoring

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Amazec Photonics ,Catharina Onderzoeks Fonds;Amazec

Intervention

Keyword: Cardiac output, Circulating blood volume, Indicator dilution curve, Photonics

Outcome measures

Primary outcome

The primary hypotheses to be tested are:

(1) a reproducible 1st thermal IDC,

(2) at least 1 recirculation thermal IDC

can be measured with the FBG photonic sensor in both the peripheral and nasal

position after a single injection of 10 ml cold (approx 4 degrees Celsius) 0.9

% saline intravenously.

Secondary outcome

The secondary hypotheses to be tested are:

- there is a linear correlation between (the change) of the area under the

curve of the primary thermal IDC measured by the FBG photonic sensor, with the

change of the Stroke Volume and Cardiac Output measured by a validated

non-invasive measurement in three positions of the Tilt-Table Test;

- when there is an impact of external temperature differences (of inhaled air)

on the thermal IDC measured by the FBG photonic sensor, respiratory and pulse

rate signals can be derived from the 1st thermal IDC measured by the FBG

photonic sensor;

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on the thermal IDC measured by the FBG photonic sensor, respiratory and pulse

rate signals can be derived from the 1st thermal IDC measured by the FBG

photonic sensor;

Study description

Background summary

In current clinical practice, measurement of Cardiac Output (CO) is performed by injecting a cold volume intravenously and recording the corresponding downstream temperature change. This results in a so-called thermal Indicator Dilution Curve (IDC) of which the area under the curve is inversely proportional to CO. With conventional electronic temperature sensors, the IDC is measured once, because - after passing through the microvascular system of the body, temperature has dropped below the detection-limit. However, using photonic Fiber Bragg Grating (FBG) sensors, the detection limit and dynamic range of the sensor have increased. This results in detecting the IDC that has passed through the microvasculature of the body for a second and possibly third time. The measurement of these recirculation curves permits measurement of the Circulating Thermal Volume (CTV), which is closely related to Circulating Blood- or Plasma Volume. In addition, the Ejection Fraction (EF) of the heart can be measured.

Study objective

Proof of Principle: to assess feasibility to measure; (1) a reproducible 1st thermal IDC, (2) at least 1 recirculation IDC using the FBG photonic sensor both peripheral and nasal.

- to compare the acquired Stroke Volume (SV) and Cardiac Output (CO) from the thermal Indicator Dilution Curve (IDC) measured by the FBG photonic sensor, with a validated non-invasive measurement in three positions of the Tilt-Table Test.

- to evaluate the impact of external temperature differences (of inhaled air) on the thermal IDC measured by the FBG photonic sensor

- to evaluate whether respiratory and pulse rate signals can be derived from

the 1st thermal Indicator Dilution Curve (IDC) measured by the FBG photonic sensor.

Study design

In this feasibility study with human volunteers, the FBG photonic sensor is used to perform measurements on the skin overlying the radial artery, and in the nose. Measurements are performed by breathing air of body temperature and air of room temperature, and with the human volunteer lying in three different positions (neutral, Trendelenburg and anti-Trendelenburg). In total, 15 measurements will be performed; each time after intravenous injection of a bolus of 10 ml cold (4 °C) 0,9% NaCl in the (contra-lateral) arm. The objective of this study is to assess feasibility to measure; (1) an accurate thermal IDC, (2) at least 1 recirculation IDC using the FBG photonic sensor both peripheral and nasal. A Clearsight hemodynamic monitoring device will be used for non-invasive continuous finger cuff reference measurements (Standard of Care).

Study burden and risks

Anticipated clinical benefits:
The results of this study may be important for future patients who need to undergo hemodynamic measurements. If results are positive, a less invasive and better quantification of cardiac output and ejection fraction of the left and right ventricle could be provided in comparison with the current standard of care which includes intra-arterial hemodynamic measurements.

Anticipated adverse device effects:
There are no anticipated adverse events related to the use of the investigational device on itself. This includes the use of the FBG photonic sensor on the skin overlying the radial artery. However, for the nasal measurements performed by the photonic sensor, there is a small risk that nasal tissue injury, pain and/or inflammation could occur.

Residual risks associated with investigational device, as identified in risk analysis report:
None

Risks associated with participation in clinical study:
There is a small, anticipated risk for study participants (with a risk classification of negligible risk) associated with the administration of intravenous cold bolus injections of 10 ml 0.9% saline. However, adverse events appear to be transient, mild, and rare. These mostly consist of inflammation of the vein (phlebitis), local pain and/or bruising at the injection site.

Possible interactions with concomitant medical treatments:
None

Steps that will be taken to control or mitigate risks:
In case there are any adverse events resulting from participation in this study, the study participants can be directly taken care of in the Catharina Hospital Eindhoven since the study will be performed in this hospital.

Risk-to-benefit rationale:
There have been no direct benefits identified for any of the volunteers. However, the results of this study may be important for future patients who need to undergo hemodynamic measurements. Positive results could eventually lead to a less invasive method and better quantification of these measurements, in comparison to current clinical practice.

Moreover, the burden of the investigation is low and acceptable. As a result, the benefits of the use of the investigational device outweigh the risks.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

have an age of 18 years or older
have signed informed consent
be health, demonstrated by the use of apre-operative anesthesiology questionnaire

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
any contraindication to multiple injections of 10 ml cold (approx 4 degrees Celsius) 0.9 % saline intravenously
any contraindication to position a sensor nasally (for 15 minutes)
incapable of understanding the language in which the information is given.

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):	01-11-2023
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Femto 1

Registration:	No

Ethics review

Approved WMO Date:	16-10-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-09-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84737.100.23