Tracking fluid challenges non-invasively with thoracic impedance cardiography derived CO and pleth variability index

Published: 24-04-2018
Last updated: 12-04-2024

To obtain raw COqCO data for subsequent optimization of its working algorithm and to assess the agreement of COqCO with reference CO values in patients under general anaesthesia in whom fluid is administered. A secondary objective is to study the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48578

Source
ToetsingOnline

Brief title
TICO-PVI001

Condition

- Other condition

Synonym
fluid changes during surgery

Health condition

monitoring van bloedsomloop tijdens anesthesie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fluid changes, plethysmographic variability index, thoracic impedance cardiography

Outcome measures

Primary outcome

Raw COqCO data, which includes impedance variables, will be collected as a

database and used for optimization and validation of the qCO algorithm

Also, the absolute value of RPVI, as obtained by the Masimo Radical 7 monitor,

and its fluid-induced change (*RPVI) will be assessed, in comparison to its

clinical reference, SVV.

Secondary outcome

- Comparison of the prediction of fluid responsiveness by RPVI with both

FloTrac/EV1000-derived SVV and traditional PVI.

- Ability of RPVI to predict fluid responsiveness, defined as an increase in CO

> 15%, and comparing it with the ability of SVV to predict fluid

responsiveness.

- Ability of SpHb to track changes in Hb concentration following fluid

administration by comparing it to reference (satellite-lab) Hb values.

Study description

Background summary

Technologic advances allow cardiac output (CO) to be monitored completely noninvasively using impendance cardiography (COqCO). Also, cardiac preload dependency can be assessed noninvasively using variations in plethysmography (RPVI). In patients under general anaesthesia in whom fluid is administered, the agreement of COqCO with clinical reference CO values is unknown, as well the ability of RPVI to assess changes in preload dependency.
Previously, we have assessed the agreement of non-invasively determined Hb concentration (SpHb) during ongoing liver surgery.12 Recent technical advances have led to an update in the SpHb sensor and its underlying algorithm. The effect of fluid administration on the reliability of SpHb in its current version by comparing it with reference Hb values (i.e. satellite-lab Hb; ABL90 Flex, Radiometer, Copenhagen, Denmark), has not been assessed yet

Study objective

To obtain raw COqCO data for subsequent optimization of its working algorithm and to assess the agreement of COqCO with reference CO values in patients under general anaesthesia in whom fluid is administered. A secondary objective is to study the influence of fluid administration on the ability of RPVI to reflect preload dependency and to study the influence of a standardized fluid administration on non-invasively measured haemoglobin concentration (SpHb).

Study design

Single-centre, low-risk, non-invasive interventional prospective study

Intervention

After induction of anaesthesia and once a steady state haemodynamic phase has been reached before incision, all patients will be administered 5ml kg-1 crystalloids i.v. in 5-10 minutes. The haemodynamic response will be evaluated by measuring COqCO, RPVI and the respective reference values, i.e. FloTrac/EV1000 TM derived CO and stroke volume variation (SVV), respectively.

Study burden and risks

The sensors used for monitoring COqCO and RPVI are completely noninvasive and pose no additional harm to the patient. Since only patients will be included in whom no severe cardiopulmonary comorbidity is present, the risk of cardiac decompensation secondary to the administration of 5 ml kg1- crystalloids is negligible.
For evaluating SpHb changes, 2 blood samples (about 2.5ml each) will be drawn before and after the fluid administration, from an indwelling arterial catheter, of which the placement is standard care.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients scheduled for elective non-cardiac surgery requiring invasive arterial blood pressure monitoring.
* Patients older than 18.
* ASA physical status I-III.
* Informed and willing to give written informed consent.

Exclusion criteria

* Patients who refuse to participate.
* Patients unable to consent (i.e. severe mental disorder, younger than 18).
* Patients with pacemakers.

* Patients with severe cardiac pathologies or hemodynamically unstable.
* Patients with end-stage renal failure.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-03-2021
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Quantium Medical qCO monitor; Masimo Radical 7 monitor and its sensor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-04-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL65093.042.18