Tracking fluid challenges during surgery

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26946

Source
Nationaal Trial Register

Brief title
TICO-PVI001

Health condition

Anesthesiology;thoracic impedance cardiography derived cardiac outpout; pleth variability index
Anesthesie; cardiac output afgeleid van thoracale impedantie cardiografie; pleth variabiliteitsindex

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

The main study endpoint is the agreement of COqCO with reference CO in terms of bias, precision and trending ability. The change in RPVI will be assessed with respect to changes in SVV, to evaluate the ability of RPVI to track fluid-induced changes in preload dependency.

Secondary outcome

- Analysis of the variability of qCO derived CO during the different hypnotic conditions of the patient (awake, anaesthetic induction phase, steady state general anaesthesia).

- 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.

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.

Study objective

To assess the agreement of COqCO with reference CO values in patients under general anaesthesia in whom fluid is administered, as well as to study the influence of fluid administration on the ability of RPVI to reflect preload dependency.

Study design

From start of induction of anesthesia until end of surgery.

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.

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6852
NTR-old	NTR7030
Other	UMCG Research Register : 201800142

Study results