Echo flow versus (non-)invasive haemodynamics 2

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22829

Source
Nationaal Trial Register

Brief title
E-FLOW 2

Health condition

Adult patients (>18y), scheduled for coronary arterial bypass graft surgery and/or mono valve surgery

Sponsors and support

Primary sponsor: Amsterdam UMC location AMC
Source(s) of monetary or material Support: Philips Electronics Nederland B.V. (“Philips”)

Intervention

Outcome measures

Primary outcome

To assess the accuracy of carotid blood flow CO measurement with ultrasound compared to (1) thermodilution CO measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive CO measurement and describe if the limit of agreements are between ±30%.

Secondary outcome

To study the trending ability of carotid blood flow CO measurement with ultrasound compared to (1) thermodilution CO measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive CO measurement.

Third Objective:
To compare the precision of carotid blood flow CO measurement with ultrasound compared to (1) thermodilution CO measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive CO measurement.

Fourth Objective:
To compare the response to therapy (directional changes) of carotid blood flow CO measurement with ultrasound compared to (1) thermodilution CO measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive CO measurement.

Other Objectives:
To study the accuracy of carotid blood flow variation measurement with ultrasound compared to invasive and non-invasive stroke volume variation measurements.

Study description

Background summary

Rationale: Diligent fluid management is instrumental to improve postoperative outcome, cost, and quality of care.
Objective: To determine the accuracy of cardiac output estimated by carotid blood flow measurements using ultrasound, compared to thermodilution based cardiac output analysis, and both invasive, and non-invasive pulse-contour analysis.
Study design: Prospective observational diagnostic accuracy study
Study population: 18 adult patients, scheduled for coronary arterial bypass graft surgery and/or mono valve surgery.
Intervention: Functional hemodynamic test; end-expiratory occlusion test, inspiratory hold, passive leg raise test.
Main study parameters/endpoints: Cardiac output based on ultrasound measurements of carotid blood flow and its variations. The accuracy of these hemodynamic estimates is compared to thermodilution derived cardiac output, along with pulse-contour analysis derived cardiac output (invasive or non-invasive) after functional hemodynamic tests to induce changes in preload or systemic vascular resistance.
We will also measure continuous invasive arterial blood pressure (systolic, diastolic, and mean arterial pressure), stroke volume variation, central venous pressure, heart rate, electrocardiogram, peripheral flow index, peripheral oxygen saturation, end-tidal carbon dioxide, respiratory waveform and respiratory rate.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients participating in the study will be exposed to minimal burden as only non-invasive ultrasound measurements will be performed additional to standard of care. Only 3 measurements will be performed with the patient awake; all other additional ultrasound measurements will be performed under anaesthesia. In cardiac surgery patients, central venous cannulation and continuous intra-arterial blood pressure monitoring by cannulation of the radial, brachial or femoral artery is standard of care. In this study, we standardly perform femoral artery cannulation for transpulmonary thermodilution. Compared to radial or brachial artery cannulation, there are no additional risks.

Study objective

We aim to compare the accuracy of ultrasound derived blood flow parameters from the carotid artery to pulse-contour derived cardiac output and non-invasive cardiac output measurements. Our motivation is to develop a non-invasive, radiation-free, ultrasound flow measurement method to monitor hemodynamic parameters relevant for ICU patient's status.

Study design

First 4 hours postoperative, 8 hours postoperative, one day postoperative

Intervention

We will perform non-invasive ultrasound measurements of the carotid blood flow in ICU patients, before and after events that are expected to change preload or SVR, that may also result in change of cardiac output. We will collect simultaneously data from blood flow measurements and invasive and non-invasive pressure waveforms together with pulse-contour data. The events involve functional hemodynamic tests, passive leg raise tests, positional changes, administration of fluids, and discontinuation of sedation or vasopressors.

Contacts

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Eligibility criteria

Inclusion criteria

To be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult patient (age > 18 years)
- Elective coronary arterial bypass graft surgery and/or mono valve surgery
- Informed consent

Exclusion criteria

A subject who meets any of the following criteria will be excluded from participation in this study:
- Significant aortic valve stenosis > 30% without indication for valve repair, or abnormal anatomy of aortic, femoral, carotid or brachial artery 12
- Postoperative severe aortic valve regurgitation or stenosis > 30%
- Atrial fibrillation or arrhythmias
- Cerebrovascular accident
- COPD GOLD 3 or 4
- Inability to measure carotid artery blood flow
- Carotid bifurcation anatomically to low
- Contra-indications for femoral arterial catheter placement (e.g., vascular graft)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	10-06-2021
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Deidentified individual clinical trial participant-level data will be shared with Philips Electronics Nederland B.V. (“Philips”) where it will only be used for research and development purposes.
This includes non-invasive cardiac output measurements, invasive cardiac output measurements, and blood flow measurements from the carotid artery. Data transfer from our hospital to Philips will take place after each completed inclusion via portal https://filesender.surf.nl/. Large data files from the ultrasound device will be downloaded to a secure portable hard drive every two to three weeks.

Ethics review

Positive opinion Date:	20-10-2021
Application type:	First submission

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	NL9804
Other	METC Amsterdam UMC location AMC : 2020_282, NL75839.018.20

Study results

Summary results

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