Echo flow versus (non-)invasive haemodynamics 2

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22829

Bron
NTR

Verkorte titel
E-FLOW 2

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam UMC location AMC
Overige ondersteuning: Philips Electronics Nederland B.V. (“Philips”)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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%.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Amsterdam UMC locatie AMC
Santino Rellum

0683060411

Wetenschappelijk

Amsterdam UMC locatie AMC
Santino Rellum

0683060411

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-06-2021
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	20-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9804
Ander register	METC Amsterdam UMC location AMC : 2020_282, NL75839.018.20

Resultaten

Samenvatting resultaten

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