The accuracy of ultrasound derived carotid artery flow compared to conventional intravascular methods

Published: 24-02-2021
Last updated: 08-04-2024

To determine the accuracy of cardiac output (CO), estimated by carotid blood flow measurements using ultrasound, compared to CO estimated by PICCO thermodilution, or invasive or non-invasive pulse-contour analysis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON49326

Source
ToetsingOnline

Brief title
E-FLOW 2

Condition

- Cardiac disorders, signs and symptoms NEC
- Decreased and nonspecific blood pressure disorders and shock

Synonym
blood flow measurements, non-invasive cardiac output monitoring

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf Philips,Philips

Intervention

Keyword: Cardiac output, Measurements, Reproducibility of results

Outcome measures

Primary outcome

The accuracy of CO measured by ultrasound of the carotid blood flow will be compared to (1) thermodilution cardiac output measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive cardiac output measurement. These measurements are performed shortly after defined events in ICU patients when changes in the SVR are expected.The accuracy will be assessed by Bland-Altman analysis. We will describe if the limit of agreements are between ±30%.

Secondary outcome

- The variability or trending capability of CO measured by ultrasound of the carotid blood flow will be compared to (1) thermodilution cardiac output measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive cardiac output measurement calculated by concordance analysis and polar analysis, in short change in CO by ultrasound compared to change in CO by the reference CO. 13

- The bias of carotid blood flow measurement with ultrasound compared to (1) thermodilution cardiac output measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour based non-invasive cardiac output measurement calculated by Bland-Altman analysis and mean error. 13

- The response to therapy (directional changes) of carotid blood flow

measurement with ultrasound compared to (1) thermodilution cardiac output

measurement, (2) pulse-contour cardiac output measurement and (3) pulse-contour

based non-invasive cardiac output measurement calculated by polar analysis. 13

Study description

Background summary

Diligent fluid management is instrumental to improve postoperative outcome, cost and quality of care.

Study objective

To determine the accuracy of cardiac output (CO), estimated by carotid blood flow measurements using ultrasound, compared to CO estimated by PICCO thermodilution, or invasive or non-invasive pulse-contour analysis.

Study design

Prospective observational diagnostic accuracy study

Study burden and risks

Patient burden is considered to be minimal (the collection of general data from hospital charts and (electronic) medical records, measurements are mostly performed when anaesthetised, duration of anaesthesia is no longer than standard operating procedure; no additional arterial/venous punctures, no additional risk of femoral artery cannulation opposed to radial or brachial artery cannulation, recovery after surgery is not affected by any of the study components).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult patient (age > 18 years)
- Elective coronary arterial bypass graft surgery and/or valve surgery
- Informed consent

Exclusion criteria

- Significant aortic valve stenosis > 30% without indication for valve repair, or abnormal anatomy of aortic, femoral, carotid or brachial artery 16
- Cerebrovascular accident
- Atrial fibrillation or arrhythmias
- COPD stage 3-4
- Severe heart valve regurgitation or stenosis
- Inability to measure carotid artery blood flow or too low bifurcation
- Contra-indications for femoral arterial catheter placement (e.g., vascular graft)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2021
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	24-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	07-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT04593797
CCMO	NL75839.018.20