A clinical study to compare Continuous Arterial-pressure-based (FloTrac), Transoesophageal doppler ultrasound, thoracic bioreactance (Nicom) Cardiac Output Measurements in low cardiac output states

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON40414

Source
ToetsingOnline

Brief title
CATCOM study

Condition

- Heart failures

Synonym
shock

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac output, comparison, non invasive

Outcome measures

Primary outcome

To establish the bias, level of agreement and percentage error of the different

non-invasive cardiac output measurements compared with the invasive gold

standard (intermittent thermodilution).

Secondary outcome

Not applicable

Study description

Background summary

Individualized treatment of hemodynamic instability is thought to improve patient outcome. Therapy is based on exact measurement and monitoring of hemodynamic parameters amongst cardiac ouput is an important one. Pulmonary artery catheter based cardiac output measurement is considered the gold standard but is an invasive procedure. Other non-invasive methods have been developed and they seem to have a good correlation with invasive measurements but within the normal range. Although there are conflicting results and questions are raised about the used methodology. Because decision making depends on the reliability of data we set out to investigate the reliability of different non invasive cardiac output measurements in low output states in coronary artery bypass graft surgery.

Study objective

The primary objective of this trial is to investigate the bias, limits of

agreement and percentage error of cardiac output measurements with Vigileo FloTrac, transoesophageal doppler ultrasound, thoracic bioreactance (NICOM) with the CO obtained from pulmonary artery catheter thermodilution measurements in low cardiac output states.

Study design

mono centre interventional study.

Intervention

CPAP manoeuvres consisting of 3 cycles of 5 minutes of 10, 15 and 20 cm H2O respectively. A pulmonary artery catheter will be inserted transjugularly.

Study burden and risks

There is a risk associated with insertion of a pulmonary artery catheter. The risk of persistent ventricular arrhythmias requiring lidocaine is 3%. None of whom suffer hemodynamic instability. Other arrhytmias are very rare. There is a 5% chance of developing transient right bundle branch block, placing patients with a left bundle branch block at risk of a complete hart block. Knotting of the catheter can occur during insertion if loops are allowed to form within one of the cardiac chambers. This can generally be avoided if the individual passing the catheter is careful not to exceed the expected distance from the insertion point to the right ventricle or pulmonary artery. When knotting occurs, the catheter can usually be removed transvenously. However, some patients require placement of a guidewire, venotomy, or even surgical extraction. The most dangerous complication with pulmonary artery catheters is associated with wedging of the pulmonary artery to determine pulmonary artery wedge pressure (PAWP) as a representative/surrogate of the left ventricle end diastolic pressure (LVEDP). The incidence of this rare complication is about 0.03%. In this study no PAWP will be determined. There is no pulmonary risk associated with CPAP manoeuvres up to 20 cm H2O in patients with no pulmonary disease. In lung recruitment studies airway pressures up to 40-50 cm H2O are probably harmful but in lung protective ventilation studies pressures up to 30 cm H2O are considered to be safe. In studies using CPAP manoeuvres to influence venous return similar pressures (20 cm H2O) have been used with no adverse effects. Transesophageal ultrasound probe insertion is a common procedure and complications are infrequent provided care is exercised and contraindications are respected. Reported complications are: odynophagia (0,1%), upper gastrointestinal haemorrhage (0,03%), oesophageal perforation (0,01%), dental injury (0,03%) and endotracheal tube malposition (0,03%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients scheduled for elective coronary artery bypass grafting (CABG) without valve surgery provided with informed consent

Exclusion criteria

- Prior cardiac surgery (Re-operations)
- Absence of sinus rhythm
- Left main disease
- Canadian class IV angina pectoris
- Carotid stenosis > 50%
- MDRD clearance < 60 ml/min

- Central or peripheral vascular disease or surgery
- Age <18 years
- Left ventricular ejection fraction *30%
- Right heart mass (thrombus and/or tumor)
- Tricuspid or pulmonary valve insufficiency
- Left bundle branch block
- Serious pulmonary disease (resting SpO2 < 90% at room air)
- bullous emphysema
- Oesophageal stricture
- Oesophageal tumor
- Oesophageal diverticula
- Oesophageal scleroderma
- Recent upper gastrointestinal surgery
- Oesophageal varices

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Continuous Arterial-pressure-based cardiac output (FloTrac Vigileo);Transoesophageal doppler ultraso
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL46013.100.13