Minimally invasive determination of oxygen extraction ratio in patients undergoing cardiac surgery

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What is the level of agreement between the gold standard, which includes invasive DO2 and VO2 measurements (with pulmonary artery catheter and central venous line), when compared with DO2 and VO2 measurements derived by a minimal invasive approach (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON42604

Source
ToetsingOnline

Brief title
VooDoo study

Condition

- Cardiac therapeutic procedures

Synonym
Cardiac surgery, open heart surgery

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac surgery, Oxygen consumption, Oxygen delivery

Outcome measures

Primary outcome

Invasive and minimal invasive measurements of DO2, VO2 and the oxygen

extraction ratio.

Secondary outcome

* Cardiac output

* Hemoglobin measurements in the laboratory and using a point of care device

* SpO2

* SaO2

* SvO2/ScvO2

* O2ER

* Lactate

Study description

Background summary

The balance between tissue oxygen delivery (DO2) and oxygen consumption (VO2) is indicative for tissue metabolism and local oxygen requirements. Unfortunately, DO2 and VO2 measurements are limited to settings where patients receive intensive invasive hemodynamic monitoring, such as cardiosurgical procedures or the intensive care unit. In this study, we aim to validate a minimal invasive approach to assess the DO2 and VO2 using Nexfin-based cardiac output measurements, point-of-care hemoglobin measurements and SaO2 measurements by pulse oximetry, and inspiratory and expiratory O2 levels for the calculation of VO2. The obtained values will be compared with DO2 and VO2 levels derived from the gold standard approach that includes an invasive pulmonary artery catheter and central venous line.

Study objective

What is the level of agreement between the gold standard, which includes invasive DO2 and VO2 measurements (with pulmonary artery catheter and central venous line), when compared with DO2 and VO2 measurements derived by a minimal invasive approach (using pulse oximetry, Nexfin, cardiac output, inspiratory and expiratory O2 levels), in patients undergoing cardiac surgery?

Study design

* Single center, observational study in patients who are scheduled for elective cardiac surgery with a pulmonary artery catheter and central venous line.
* Parallel measurements of invasive and non-invasive parameters that are required to calculate DO2 and VO2.
* Study measurements take place during anesthesia and surgery
* Study procedures include pulse oxymetry, blood sample measurements and cardiac output determination.

Study burden and risks

There are no benefits nor risks associated with the present study proposal. A total of 20 ml of extra blood will be drawn from an existing intravascular catheter while the patient is under anesthesia. The use of a central venous line and pulmonary artery catheter are part of routine clinical practice in patients undergoing cardiac surgery with cardiopulmonary bypass.

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

* Elective cardiac surgery
* Older than 18 years
* Presence of a pulmonary artery catheter and central venous line

Exclusion criteria

* Re-operation
* Aortic valve surgery in cas of severe aortic stenosis
* Bentall surgery
* Arrhythmias (may dampen the signal of pulse oximetry)
* Anemia (Hemoglobin levels of 5.5 mmol/L or lower; decreases oxygen delivery)
* Severe COPD (adaptation of peripheral microvasculature to chronic hypoxia; Gold 3/4)
* Intra-cardiac shunt
* ASA score of 4 and higher and NYHA score exceeding 4

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):	29-09-2015
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Nexfin arterial blood pressure measurement; Hemocue Point-of-care hemoglobin measurement
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-11-2015
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
CCMO	NL53854.029.15