Comparison of cerebral tissue oxygen desaturation in patients undergoing on-pump or off-pump coronary artery bypass grafting

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38255

Source
ToetsingOnline

Brief title
Tissue oxygenation during heart surgery

Condition

- Coronary artery disorders
- Cognitive and attention disorders and disturbances
- Cardiac therapeutic procedures

Synonym
coronary artery disease, coronary atherosclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brain metabolism, Coronary artery bypass surgery, Oximetry

Outcome measures

Primary outcome

The primary endpoint of this study is the incidence of significant brain tissue oxygen desaturation, defined as AUC40 (area under the curve, area above the saturation curve and below the 40% upper limit) of > 600 %.sec, a function of both duration (in seconds) and severity (% < 40) of desaturation. This cut-off value was found to be predictive of postoperative cognitive dysfunction in a previous study.

Secondary outcome

• Baseline cerebral StO2

• Change in baseline cerebral StO2 after breathing 100% O2 for 5 mins

• Thenar muscle and renal StO2

• Other metrics of cerebral, renal and thenar muscle tissue oxygen desaturation (calculated from the trend in StO2 over time) such as lowest recorded SctO2, AUC50

• Incidence of postoperative cognitive dysfunction (defined as a combined Z-score for all tests >2 or a Z-score >2 in >2 individual tests)

• Plasma concentrations of biomarkers of inflammation and neurological injury: IL-6, TNF-α, NSE and carnosinase

• Urine concentration of biomarkers of acute renal injury: KIM-1 and NGAL.

• Plasma creatinine; incidence of renal failure

Study description

Background summary

Coronary artery bypass grafting (CABG) is currently the preferred treatment for disease of the coronary artery main stem or of multiple coronary vessel disease, but is often associated with complications, including post-operative cognitive dysfunction and impaired renal function. For a long time it was assumed that these complications were caused by impaired tissue oxygenation (StO2) caused by the physiological alterations associated with cardiopulmonary bypass (CPB). For this and other reasons the technique of *off-pump* CABG surgery was developed, in which the grafts are implanted with the heart beating and no artificial circulation through the CPB machine, with the aim of preventing these physiological derangements, and thereby reducing the incidence of mortality and major complications. Recent studies have however failed to show long-term benefits of off-pump surgery, but with regard to renal function and POCD they have used insensitive and controversial methods that may have been unable to detect fine differences. Recently it has become possible to measure tissue oxygenation (StO2) non-invasively using commercially available monitors that use near infra-red spectroscopy (NIRS) to assess tissue oxygen levels. The levels are physiologically highly relevant since they reflect the overall balance between blood flow, blood oxygen content, and tissue oxygen uptake and requirements. The aim of this study is to use NIRS monitors to determine if there is a difference in cerebral, renal and peripheral tissue oxygenation between on- and off-pump CABG surgery.

Study objective

The goal of this study is to determine if off-pump CABG surgery is associated with better cerebral tissue oxygenation when compared with on-pump CABG. In addition, we would like to compare the results of two different monitors of brain tissue oxygenation with each other, and assess the correlation between brain tissue oxygenation and oxygenation measurements in renal and muscular tissue, as well as with conventional hemodynamic and metabolic variables, such as central venous oxygen saturation (ScvO2). Finally, we aim to determine if duration and extent of cerebral oxygen desaturation predicts outcome variables such as postoperative cognitive performance.

Study design

Prospective, randomised, observational trial.

Study burden and risks

Besides the randomisation to either on-pump or off-pump surgery, no interventions will be performed. Only patients who are eligible for both surgical techniques are included and randomised.
Due to the observational character of this study and the non-invasive measurements, the risks involved are negligible. In addition to standard care, 4 sensors will be noninvasively attached to the skin by using adhesive plasters. Theoretically, patients could potentially be allergic to this adhesive and will be asked for any previous events during the visitation on the ward. If a patient is indeed allergic to the type of sticker that will be used, he will be excluded from the study. An additional approximately 30-35 ml of blood will be drawn for analysis of oxygen saturation and biomarkers. This should not have any consequences for the patient, since the normally encountered blood loss during CABG surgery is ~500-1000 ml.

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

Age >=18 years
Informed patient consent
Coronary artery disease suitable for both on-pump and off-pump CABG surgery.

Exclusion criteria

History of head trauma or stroke causing significant active neurologic disease
History of neurosurgery
Severe or symptomatic carotid artery disease
Requirement for valve surgery in addition to CABG
Pre-existing acute or chronic renal dysfunction
Urgent or emergency surgery
Difficulty with cognitive testing: impaired hearing or eyesight, poor Dutch language comprehension, disability impairing the usage of the hand or arm.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	15-06-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	29-10-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL35770.042.11