Is there an improvement of microcirculation regarding propofol vs. sevoflurane anaesthetic regimen during coronary artery bypass grafting?

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Ethical review	Not approved
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON30260

Source
ToetsingOnline

Brief title
SEVOMICAB

Condition

- Coronary artery disorders

Synonym
coronary artery disease, occlusive vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Anesthesiologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CABG, microcirculation, propofol, sevoflurane

Outcome measures

Primary outcome

5.1 Endpoints:

5.1.1) Myocardial cell damage markers (Troponin I, CK, CK-MB) between both

groups on T(0) to T(7).

See protocol for Time intervals (T)

Secondary outcome

5.1.2) Hemodynamic data, for example CO, CI, SV, SVR, PVR on T (0) to T(3).

5.1.3) Microcirculation as measured by MFI on T(0) to T(5).

5.1.4) Inflammatory markers (for example: leucocytes, CRP, TNF-a, IL-6,

CD11b/CD18 cells).

Study description

Background summary

In general, anesthesia is conducted with intravenous agents or with volatile agents which are delivered by inhalation. Each way has its advantage, as for example volatile agents are usually administered to paediatric patients to prevent mental distress by placing an intravenous line.
The purpose of this study is to investigate whether administration of sevoflurane during coronary artery bypass grafting (CABG) will improve the microcirculation when compared to propofol. Recent studies have emphasized that halogenated volatile anesthetic agents, including sevoflurane (Sevorane®, Abbott, Hoofddorp, The Netherlands), exert cardioprotective effects by means of ischemic preconditioning (IPC)1-11. This reduces both the incidence of ischemia and myocardial infarction size. In addition to the preconditioning effect, volatile anesthetics suppress neutrophil-endothelium interaction and reduce the

inflammatory response after cardiopulmonary bypass (CPB)12,13,14,15 . Recent studies show lower postoperative release of troponin I and an improvement of cardiac output (CO) compared to patients receiving propofol for the same procedure.10,11,16 Whether changes in the inflammatory response are solely responsible for the difference observed between propofol and sevoflurane remains unclear. Moreover, whether the microcirculation is changed during sevoflurane regimen and whether this is a direct influence or a result of a blunted inflammatory response, is our study of interest.
This study is an observational study. Our purpose is not to explain the possible mechanism between inflammatory factors, microcirculation and sevoflurane or propofol.

Study objective

1.) First, we hypothesize that a reduction of myocardial damage explained by lower levels of myocardial damage markers (e.g. troponin I, CK-MB) by sevoflurane may be related to a reduction of inflammatory mediators (i.e. TNF-α, CD11b/CD18 cells, and IL-6), which in turn may result in better haemodynamic parameters (e.g. CO, stroke volume and CI)
2.) Second hypothesis is to ascertain the changes of the microcirculation with the orthogonal polarization spectroscopy17 (OPS) (Cytometrics, Philadelphia, USA) imaging device (see below) between sevoflurane and propofol.
3.) The third hypothesis is that a reduced inflammatory response to CPB with sevoflurane will attenuate the generation of cytokines or reduce activation of inflammatory cells explained by a reduction in the generation of TNF-α, CD11b/CD18 cells, and IL-6. Attenuation of the inflammatory response by sevoflurane may be translated in an improved microcirculation (as measured by the OPS device, see below) compared to patients with a propofol regimen.

Study design

This study is a prospective singe-blinded randomised trial. Patients who are scheduled to undergo elective CABG will be included. Approval of the study by the hospital*s Medical Ethics Committee (St. Antonius hospital, Nieuwegein, The Netherlands) is a pre-requisite. When approved, informed consent will be obtained and adult patients undergoing CABG will be identified by a study-code. The patients will be randomised to either the propofol or sevoflurane group, meaning that after induction of anesthesia, throughout the procedure only sevoflurane or propofol will be administered. Both agents are used as anesthetic in our clinic for this procedure as local custom. The CABG will be carried out routinely as planned. Fifty patients in total will be studied
At the end of the procedure, when transporting the patient to the ICU, propofol continuous infusion will be administered as routine. On the ICU, propofol infusion is applied until the patient is weaned from the ventilation.
When possible, operation and intensive care personnel will be blinded for randomisation. It is however inevitable that the attending anaesthesiologist

cannot be blinded for administration of either sevoflurane or propofol. The investigator who records the microcirculation cannot be blinded as well. Therefore this is a single blinded study. Three images per imaging moment will be recorded on digital videotape and analysed afterwards using a semi-quantitative method19 for analysis of Microcirculatory Flow Index (MFI). The device is gently applied without pressure on the lateral side under the tongue after removal of saliva. Minimum duration of the images is 20 seconds. For each measurement a new cap will be used over the lens for the sake of hygiene. Subsequently, the images are captured in 5 to 10 seconds representative video clips in AVI format. These video clips are analysed blindly (by a different investigator) and at random to prevent coupling between images. To score the MFI, two blinded investigators will asses the MFI independently and the mean MFI will be used as the definitive score for that particular image.

Linkage with the patient*s identity will only be possible by the researchers. Patient*s identity will be handled discretely and patient*s data will be coded. Published data will have no link with patient identity.
A pulmonary artery catheter (PAC) for measuring haemodynamic data will be inserted. This is a world-wide routine procedure for patients undergoing cardiac surgery, though in our hospital we do not insert a PAC for an elective CABG, since we believe there are no additional advantages.
Also, extra blood samples will be taken to asses biochemical parameters (see below). Assessments of microcirculation will be performed as described above. Discomfort for the patients are extra blood samples, risks associated with introduction and use of pulmonary artery catheter and OPS imaging (however, most images will be taken when patients are anesthesized).
Patients will be able to stop their participation in this study at any time they wish without consequences. Collected data at various intervals is described below.

Study burden and risks

In accordance with Dutch law, an insurance policy covering all participating patients has been effected with Medirisk insurance company. Since both propofol and sevoflurane anesthesia are world wide used for providing anesthesia, no extra risks are associated concerning anesthesia. OPS imaging performed sublingually is a non invasive tool as described, thus no additional risks are provided.
Patients participating in this study will receive a pulmonary artery catheter in order to asses the haemodynamic parameters. Associated risks are arrhythmias, ventricular fibrillation, right bundle branch block, complete heart block, thromboembolism, pulmonary infarction, pulmonary artery rupture, pulmonary artery pseudoaneurysm, endocardial damage, cardiac valve injury and endocarditis.21 Furthermore, extra blood samples (maximal 100 ml) as described above will be taken from patients participating in this study.

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

All patients undergoing elective CABG are included.

Exclusion criteria

Exclusion criteria includes emergency surgery, recent myocardial infarction (less than 7 days old), concurrent valve surgery or redo CABG, chronic use of either corticosteroid medication or NSAIDS.

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Pulmonary Artery Catheter;Orthogonal Polarization Spectroscopy
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	13-04-2007
Application type:	First submission
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	NL14831.100.06