A single blinded randomised, crossover, individual comparison on cardiac performance of xenon vs. sevoflurane inhalation in humans undergoing coronary artery bypass grafting

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The aim of this study is to evaluate the immediate effect of xenon inhalation on cardiac performance in patients scheduled for CABG surgery in comparison with the effect induced by sevoflurane inhalation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON31231

Source
ToetsingOnline

Brief title
A study on effects of xenon inhalation in humans undergoing CABG; part I

Condition

- Coronary artery disorders

Synonym
CABG

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CABG, Echo (TEE), Xenon

Outcome measures

Primary outcome

The primary endpoint is defined as the change in cardiac performance, defined

as cardiac function index (PICCO) and contractility index (TEE).

Secondary outcome

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Study description

Background summary

In 1951 the first results were published about the use of xenon as an anaesthetic agent in humans undergoing surgery. Over the years many papers were published, which covered several aspects of the properties of xenon in anaesthesiology. It is frequently claimed that xenon is an ideal anaesthetic agent as it is inflammable, with low toxicity, and devoid of teratogenic effects. Moreover, induction and recovery are rapid and consequently permit good anaesthetic control. Xenon is registered as a medical gas in the European Community since April 2007.
Over the last years, papers are being published reporting that xenon has relatively few, minor side effects. From our own study group a case report about the use of xenon for Eisenmenger*s Syndrome was published to illustrate its cardiovascular stability.
Recently, our study group has participated also in two multi-centre trials in which xenon was used as an anaesthetic agent and compared to isoflurane anaesthesia. The first study evaluated the efficacy and safety of xenon inhalation in patients who had to undergo elective surgery. In the second study cardiac performance was studied using a transoesophageal echocardiography (TEE) after inhalation of xenon in patients without cardiopulmonary disease scheduled for elective general surgery. Cardio depressive effects were observed after

isoflurane anaesthesia, whereas the occurrence of haemodynamic side effects was diminished during xenon anaesthesia. From these results, it has been suggested that the administration of xenon could be a therapeutic option when given to cardiac risk patients. Therefore, we like to study the effect of xenon inhalation on the cardiac performance in patients scheduled for elective coronary artery bypass grafting (CABG).

Study objective

The aim of this study is to evaluate the immediate effect of xenon inhalation on cardiac performance in patients scheduled for CABG surgery in comparison with the effect induced by sevoflurane inhalation.

Study design

This study is designed as a single-blinded, prospective, single-centre, crossover, and randomised, controlled clinical study. The total number of patients enrolled will be 20.

Intervention

Patients in Group A will at first receive 1 MAC Sevoflurane in O2/Air, followed after a 20-min period by measuring the contractility index using TOE. Then, Sevoflurane will be washed out and 65% xenon (together with O2) will be washed in, followed again after a 20-min period with measurement of contractility index by using TOE. Thereafter xenon will also be washed out.
Patients in Group B will be examined in the same way, however, the sequence of the drugs is opposit, thus at first, wash-in of xenon and after washout followed by washin and washout of sevoflurane.

Study burden and risks

Patients will come to operating theatre 1 hour prior to surgery to receive general anesthesia. In this hour we will look at the contractility of the heart with TEE.

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 range: 18 years and older, Patients who have to undergo elective cardiac surgery (CABG with or without valve surgery), Written informed consent

Exclusion criteria

Age range: < 18 years, Emergency operations, Pregnancy, Severe COPD, Informed written consent missing, SaO2 < 90% (room atmosphere), Presumed non-cooperatives, Legal incapacity, Any clinical condition which does not justify study participation in the investigator's opinion

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Sevorane
Generic name:	Sevoflurane
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xenon
Generic name:	Xenon
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	16-10-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	14-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2007-005415-25-NL
CCMO	NL18780.078.07