The effect of sevoflurane and isoflurane on vasopressor need

Published: 08-10-2008
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Aim of this study is to determine the effect of isoflurane versus sevoflurane on blood pressure and systemic vascular resistance.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Decreased and nonspecific blood pressure disorders and shock
Study type	Interventional

Summary

ID

NL-OMON32879

Source
ToetsingOnline

Brief title
ESIVAN study

Condition

- Decreased and nonspecific blood pressure disorders and shock

Synonym
hypotension, low blood pressure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anesthetics, isoflurane, sevoflurane, vasopressor

Outcome measures

Primary outcome

Primary outcome measure is the total amount of the vasopressor phenylephrine that is needed to maintain blood pressure above 60 mmHg during 10 minutes of CPB.

Secondary outcome

Secondary outcome measures are mean blood pressure throughout the 10 minute periods, the need for a stronger vasopressor (norepinephrine) and the inability to keep mean blood pressure below 75 mmHg at MAC 0.6.

Study description

Background summary

In modern anesthesia a variety of volatile anesthetics is available. To decide which anesthetic should be used in different settings, it is relevant to know the beneficial and side effects of these anesthetics.
An ideal volatile anesthetic agent should have a number of qualities, which all contribute to the ease of use and the safety of the patient.
Like virtually all anesthetics, volatile anesthetics are known to decrease blood pressure. During cardiac surgery, and especially during open-heart surgery with the use of the cardiopulmonary bypass, maintenance of adequate blood pressure is important, because severe hypotension is associated with poor clinical outcomes.

At present both isoflurane and sevoflurane are frequently used in cardiac anesthesiology.
It is unclear, however, to which degree isoflurane and sevoflurane decrease blood pressure and whether this effect is predominantly caused by depression of myocardial contractility or a decrease in systemic vascular resistance (SVR).
The decision as to which of both volatiles should be used during cardiac surgery is therefore not evidence-based, but is based on personal preference of the anesthesist.

At present the number of studies comparing the influence of isoflurane and sevoflurane on blood pressure and systemic vascular resistance is limited.

Moreover, the results presented in the available literature are inconsistent. Although most publications did not report any significant difference between isoflurane and sevoflurane, a small number of publications did find a possible beneficial effect on blood pressure of sevoflurane, compared to isoflurane.

Cardiopulmonary bypass (CPB) offers an unique opportunity to study the effect of anesthetics on SVR, without concurrent effect of changes in cardiac output. This is because there is no contraction of the heart during CPB and other variables that might affect blood pressure, like cardiac index, body temperature, hematocrite and expired CO2, can be kept stable.

Study objective

Aim of this study is to determine the effect of isoflurane versus sevoflurane on blood pressure and systemic vascular resistance.

Study design

The study is designed as a crossover randomized double-blinded controlled single center trial.

Intervention

patients will be randomized to a 10 minute treatment with isoflurane, followed by a wash-out period, followed by a 10 minute treatment with sevoflurane, or the otherway round.

Study burden and risks

There is no substantial risk, nor are there any benefits for the participants.

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

Minimal of 18 years of age.
Patients undergoing coronary artery bypass grafting with the use of the cardiopulmonary bypass.

Exclusion criteria

Valve surgery. Combined surgical procedures. Uncontrolled hypertension. Poor left ventricular function (left ventricular ejection fraction < 30%). Renal failure. BMI > 25. History of cerebrovascular accident, transient ischemic attack or carotid artery stenosis. Participation in an other study.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2009
Enrollment:	35
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	08-10-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-11-2008
Application type:	First submission
Review commission:	METC NedMec

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	EUCTR2008-005426-37-NL
CCMO	NL24375.041.08