The Sevoflurane study, understanding the effects of Sevoflurane to improve safety and outcome of cardiac surgery

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The objective of this study is to determine if patients without heart failure receiving Sevoflurane have a different myocardial ischemia-reperfusion injury and/or systemic inflammatory response than patients who do not receive Sevoflurane.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON33476

Source
ToetsingOnline

Brief title
Sevo-study

Condition

- Cardiac valve disorders

Synonym
Ischemia-Reperfusion, restoration of bloodflow after period of restriction of bloodflow

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Department of Thoracic Surgery

Intervention

Keyword: Cardiac Surgery, Ischemia-Reperfusion, Sevoflurane

Outcome measures

Primary outcome

We want to assess the contribution of Sevoflurane on oxidative damage, complement, endothelial, thrombocyt and neutrophil activation and inflammation to human ischemia reperfusion injury. Obtained data will provide information about possible protection against ischemia reperfusion injury and the possible contribution of Sevoflurane to attenuate SIRS, leading to a decline in morbidity and mortality rates.

Secondary outcome

not applicable

Study description

Background summary

MIRI (myocardial ischemia reperfusion injury) is the paradoxical exacerbation of myocardial damage upon restoration of blood supply to previously ischemic myocardial tissue and is considered the major, inevitable, cause of tissue damage after ischemic events such as myocardial infarction and cardiac surgery. The pathophysiology of MIRI is complex and its exact mechanisms have not been fully elucidated yet. However, it is conceived that reperfusion results in endothelial damage, free radical production, complement, neutrophil and thrombocyte activation, and cytokine release, which ultimately result in an inflammatory reaction. Release of pro-inflammatory cytokines from the myocardium induced by MIRI is not limited to the organ itself but also contributes to activation of systemic vascular endothelium, clinically recognized as SIRS (systemic inflammatory response syndrome).

Study objective

The objective of this study is to determine if patients without heart failure

receiving Sevoflurane have a different myocardial ischemia-reperfusion injury and/or systemic inflammatory response than patients who do not receive Sevoflurane.

Study design

Single center observational study

Study burden and risks

The proposed study aims to optimize the surgical treatment. The measurements necessary to assess the defined study endpoints are not expected to negatively influence the result of treatment. The use of the catheter will have an insignificant risk.

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

Patients without heart failure (EF below 35%) accepted for mitral valve surgery via sternotomy

Exclusion criteria

Acceptation for minimal invasive mitral valve surgery, inability to sign informed consent, less than 18 years old, emergency operations

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	22-07-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	17-09-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	EUCTR2009-012372-27-NL
CCMO	NL28293.058.09