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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20447

Source
NTR

Brief title
The Sevo-study

Health condition

Sevoflurane, Cardiac Surgery, Inflammation, Preconditioning

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Department of Thoracic Surgery

Intervention

Outcome measures

Primary outcome

1. Factors related to the acute inflammatory response (IL-6, ICAM e.d.);

2. Factors likely involved in pathophysiology of I/R injury (cytokines);

3. Markers of myocardial injury (Trop/CK-MB).

Secondary outcome

1. Factors related to the acute inflammatory response (IL-6, ICAM e.d.);

2. Factors likely involved in pathophysiology of I/R injury (cytokines);

3. Markers of myocardial injury (Trop/CK-MB).

Study description

Background summary

In this study we will include a homogenous group to obtain information about the underlying mechanisms of influencing the inflammatory component by Sevoflurane. Obtained data will provide information about possible protection against I/R injury and the possible contribution of Sevoflurane to attenuate the inflammatory response, leading to a decline in morbidity and mortality rates.

Study objective

This study will test the hypothesis that Sevoflurane attenuates oxidative damage, complement, enothelial, thrombocyt and neutrophil activation and inflammation to human ischemia reperfusion injury of the myocardium.

Study design

Baseline, OR and ICU (till 24 hours after surgery).

Intervention

Sevoflurane will be added to the blood cardioplegia mixture in the treatment cohort. The control-cohort will receive oxygen. Addition only when Heart-lungmachine is activated.

Blook will be taken several times, starting from 1 day pre-OR to 5 days post-OR.

Contacts

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Eligibility criteria

Inclusion criteria

1. Acceptation for mitral valve surgery via sternotomy;

2. LV ejection fraction > 35%.

Exclusion criteria

1. Acceptation for minimal invasive valve surgery;

2. Use of systemic corticosteroids;

3. Inability to introduce coronary sinus catheter;

4. Inability to sign informed consent or less than 18 years old;

5. Emergency operations.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-10-2009
Application type:	First submission

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
NTR-new	NL1972
NTR-old	NTR2089
Other	METC LUMC Leiden : P09.136
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A