The POSITIVE (Pre-Operative STatin InterVEntion) study, preoperative statin intervention for valve surgery.

No registrations found.

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

Summary

ID

NL-OMON27097

Source
Nationaal Trial Register

Brief title
POSITIVE

Health condition

Cardiac surgery, postoperative inflammation

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center; Department of Cardiothoracic Surgery

Intervention

Outcome measures

Primary outcome

1. Inflammatory response (IL-6, CRP);

2. Myocardial damage (troponin);

3. Pathophysiology of ischemia/reperfusion injury.

Secondary outcome

N/A

Study description

Background summary

Medical research has shown that statins, in addition to their effects on the cholesterol metabolism, also have an anti-inflammatory effect. During cardiac surgery, the difference in protection between acute and long term administration of statins will be measured using myocardial ischemia reperfusion injury markers.

Study objective

This study will test the hypothesis that acute preoperative administration of statins will offer a better protection against MIRI than long term preoperative administration does.

Study design

1. Treatment: Acute or chronic (See above);

2. Blood samples will be drawn the day patients visit our clinic until 5 days after surgery.

Intervention

After giving informed consent patients will be randomized into:

1. Acute treatment: One dose of 40 mg simvastatin the evening before and one dose of 40 mg simvastatine the morning before surgery;

2. Long term treatment: 40 mg simvastatine for a minimum of 2 weeks prior to surgery.

Contacts

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Eligibility criteria

Inclusion criteria

Acceptation for mitral/tricuspid valve surgery via sternotomy.

Exclusion criteria

1. Statine use;

2. Acceptation for minimal invasive surgery;

3. Ablation or CABG procedures;

4. Emergency operations;

5. Clinically diagnosed heart failure or atherosclerosis;

6. Use of corticosteroids.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-01-2011
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	NL2555
NTR-old	NTR2673
Other	METC LUMC : P10.083
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Ludman et al. Pharmacology & Therapeutics 2009.
Bulhak et al. Am J Physio Heart Circ Physiol 2007.
Birnbaum et al. J Cardiovasc Pharmacol Ther 2008.
Mensah et al. J Am Coll Cardiol 2005.
Liakopoulos et al. Thorac Cardiov Surg 2006.