

The POSTIVE (Pre-Operative STatin InterVEntion) study

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This study will test the hypothesis that acute administration of statins will provide for a better protective (anti-inflammatory) effect than chronic administration. Patients used for this study have to undergo mitral and/or tricuspid valve surgery...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON34896

Source

ToetsingOnline

Brief title

POSITIVE

Condition

- Cardiac therapeutic procedures

Synonym

myocardial ischemia reperfusion injury

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiac surgery, Inflammation, Statins

Outcome measures

Primary outcome

CRP, IL-6, ICAM1, vWF, cytokines, p-selectin, CK, troponins

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. Animal studies show that the infarct size is significantly reduced after myocardial ischemia by statins. The immune response elicited by the ischemia is repressed by statins. This protective effect is probably at its best when statins are administered just before the ischemic period; the anti-inflammatory effects wear off and vanish as statins are administered chronically. This knowledge holds clinically relevant information. In order to investigate whether these differences (acute versus chronic administration) also occur in humans we will administer statins per-operatively to patients in need of open heart surgery. Open heart surgery is an excellent model for ischemia as the blood supply to the heart will be impaired for part of the operation thus eliciting myocardial ischemia. During this study the difference in protection between the acute and chronic administration of statins will be measured using myocardial ischemia reperfusion injury markers.

Study objective

This study will test the hypothesis that acute administration of statins will provide for a better protective (anti-inflammatory) effect than chronic administration. Patients used for this study have to undergo mitral and/or tricuspid valve surgery and thus will have no history of statin use. If the hypothesis proves to be valid, pre-operative administration for open heart surgery needs to be considered as well as giving patients, receiving statins, in need of open heart surgery a drug-holiday.

Study design

40 patients will be randomized into 2 different groups; one of the groups will receive acute pre-operative administration of statins, the other group will receive a long term (at least 2 weeks) pre-operative administration of statins. The results of both groups will be compared to results from other patients who underwent the same operation but without the pre-operative treatment with statins.

Intervention

simvastatin 40mg

group 1: one dose of 40mg the evening before, and one dose of 40mg the morning of the operation

group 2: one dose of 40mg a day starting a minimum of 14 days before the operation

Study burden and risks

low.

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

open mitral and/or tricuspid valve surgery

Exclusion criteria

- Statine use
- Acceptation for minimal invasive mitral valve surgery
- Inability to sign informed consent
- Less than 18 years old
- Ablation procedures
- Emergency operations
- Clinically diagnosed heart failure
- Clinically diagnosed atherosclerosis
- CABG procedures
- Use of corticosteroids (e.g. prednisone etc.)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2011
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Zocor
Generic name:	Simvastatin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	25-06-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	28-06-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	EUCTR2009-018221-79-NL
CCMO	NL31175.058.10