

The effect of high dose statins (Simvastatin 80 mg) on vascular inflammation in the abdominal aneurysm.

No registrations found.

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

Summary

ID

NL-OMON24165

Source

NTR

Brief title

SPITFIRE II

Health condition

Abdominal Aortic Aneurysm

Sponsors and support

Primary sponsor: Leiden University Medical Center

Source(s) of monetary or material Support: Self financing

Intervention

Outcome measures

Primary outcome

Aortic wall IL6, IL8 and MCP-1 levels.

Secondary outcome

1. Aortic wall cell counts;
2. Aortic wall protease expression;
3. Aortic wall transcription factor activation.

Study description

Background summary

N/A

Study objective

Independently of their lipid lowering effects statins have been shown to quench markers of vascular inflammation. In an observational study we observed a mild but dose dependent anti-inflammatory effect of intermediate dose statins on vascular inflammation. As of these observations we now propose to test the hypothesis that high dose statins have a clinically relevant effect on vascular inflammation in the abdominal aortic aneurysm.

Study design

Minimal treatment period 2 weeks prior to the surgery.

Intervention

Simvastatin 80 mg OID.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age >18;
2. Open elective AAA repair;
3. Current statin use.

Exclusion criteria

1. Statin intolerance;
2. Renal impairment (clearance <30 ml/min);
3. Liver impairment;
4. Excess alcohol consumption;
5. Any chronic inflammatory conditions;
6. Use of one or more of the following pharmaceutical agents: Itraconazol, Ketoconazol, Erytromycine, Claritromycine, Ciclosporine, Fibrates, immuo suppressives or HIV-protease inhibitors;
7. Inflammatory aneurysm.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-07-2010
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion	
Date:	08-07-2010
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	NL2283
NTR-old	NTR2410
Other	MEC LUMC / CCMO : P10.085 / NL24354.058.09 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A