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

No registrations found.

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

Summary

ID

NL-OMON25146

Source
NTR

Brief title
SPITFIRE II

Health condition

Abdominal Aortic Aneurysm

Sponsors and support

Source(s) of monetary or material Support: Fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Aneurysm wall MCP-1, IL6 and 8 levels.

Secondary outcome

Aneurysm wall cell content, proteases and inflammatory transcription factors.

Study description

Background summary

In this trial we aim to confirm preclinical evidence that statins, independent of their lipid lowering effects, reduce vascular inflammation. The study will be performed in the abdominal aortic aneurysm, a condition that is part of the atherosclerotic spectrum and that is not primarily cholesterol driven. As there is evidence that the anti-inflammatory effects of statins are dose dependent we now propose to study whether high dose statin therapy is superior to the effects of standard dose statin (samples already available).
To study putative anti-inflammatory effects, patients awaiting open elective aneurysm repair will be asked to take Simvastatin 80 mg/day in the weeks prior to operation. Aneurysm wall samples will be collected at the time of operation and the effects of high dose Simvastatin will be evaluated by comparison with control samples of patients on standard dose Simvastatin/Atorvastatin (20 or 40 mg/day) or no statin.

Study objective

We hypothese that the anti-inflammatory effects of statin therapy are dose dependent, and that the effects of high dose statin therapy on vascular inflammation are superior to standard dose statin therapy.

Study design

Time of elective aneurysm repair.

Intervention

80 mg Simvastatin started at least 2 weeks prior to the planned open aneurysm repair.

Contacts

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Eligibility criteria

Inclusion criteria

1. Abdominal aortic aneurysm;

2. Current statin use.

Exclusion criteria

1. Liver dysfunction;

2. Excessive alcohol consumption.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion Date:	13-05-2009
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	NL1702
NTR-old	NTR1812
Other	MEC LUMC : P09.005
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A