Biological and biochemical markers of aneurysm wall degradation; towards non-invasive wall strength analysis.

Published: 22-05-2007
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To identify possible in vivo biochemical and biological markers related to aneurysm wall strength.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON30536

Source
ToetsingOnline

Brief title
Biomarkers of aneurysm wall strength.

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
Abdominal Aortic dilatation, arterial bulge

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Guerbet, Roissy CdG Cedex, France

Intervention

Keyword: Abdominal aortic aneurysm, Biomechanics, Inflammation, Magnetic resonance imaging

Outcome measures

Primary outcome

1. Aneurysm wall tensile strength (N/mm).

2. Concentration of biodegrading enzymes in the aneurysm wall (arbitrary units

per milligram proteins).

3. The presence of specific glucosaminoglycans in the AAA wall and in patients

blood and urine.

4. Drop in relative MR signal intensity on USPIO enhanced MR imaging

(macrophage detection).

5. Histological presence of macrophages (field count).

Secondary outcome

1. Aneurysm diameter

Study description

Background summary

Since rupture of an Abdominal Aortic Aneurysm (AAA) is potentially lethal, prophylactic surgical repair is warranted when the risk of rupture exceeds the risk of complications following surgery. Aneurysm rupture occurs when the forces acting on the aneurysm wall (stress) surpass aneurysm wall strength. Information on both wall stress and strength might therefore improve patient selection for prophylactic repair and reduce aneurysm related mortality. Although aneurysm wall stress calculations are possible, no in vivo method exists to determine aneurysm wall strength.

Study objective

To identify possible in vivo biochemical and biological markers related to aneurysm wall strength.

Study design

Prospective, non-randomized multicentre clinical study.

Study burden and risks

Blood and urine samples will be collected both before and after aneurysm repair. A subset of 10 Patients, enrolled at the Radboud University Nijmegen or the Catharina Hospital Eindhoven, will be invited for preoperative MR imaging using intravenous USPIO. Although USPIO is a non registered contrast for MR imaging, USPIO enhanced MR is regarded safe and well tolerated. Since USPIO has to administered 24-hours before MR imaging enrolled patients will have to visit the outpatient clincic the day before MR imaging and hospital admission. Aneurysm wall specimens will be collected at the time of surgery. Resection of these excess wall specimens is safe as only a limited part of the original aneurysm wall is needed to cover the vascular prosthesis.

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

1. patients scheduled for conventional repair of an asymptomatic or symptomatic (non-ruptured) aneurysm.
2. Informed consent
3. Preoperative CT (computer tomography)

Exclusion criteria

1. Patients with a ruptured abdominal aortic aneurysm
2. Contraindication for MR imaging (metallic implants, claustrophobia).
3. Prior aortic surgery
4. Severe cardiac comorbidity (congestic heart failure/coronary artery disease)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2007
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Sinerem; Ferumoxtran-10

Ethics review

Approved WMO Date:	22-05-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2007-000214-37-NL
CCMO	NL15960.091.07