

Imaging of aneurysm wall inflammation using positron emission tomography.

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Correlation of FDG uptake and in vitro aneurysm wall tensile strength. (primary objective).
The effect of aneurysm sac depressurisation, after endovascular aneurysm repair, on aneurysm wall inflammation (secondary objective).

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

Summary

ID

NL-OMON31387

Source

ToetsingOnline

Brief title

PET imaging of abdominal aortic aneurysms.

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym

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

Intervention

Keyword: Aneurysm, Inflammation, Pathophysiology, Positron Emission Tomography (PET)

Outcome measures

Primary outcome

Standard uptake value (SUV) measurements to assess FDG uptake in the aneurysm wall and in vitro aneurysm wall strength (N/mm).

Secondary outcome

Plasma and urine levels of inflammatory biomarkers (e.g. CRP).

Study description

Background summary

Aneurysm development, progression and rupture are characterised by extensive inflammation, dominated by the infiltration of T-cells, B-cells and macrophages. Recent studies into the pathophysiology of aneurysm wall degradation suggest a close relation between increased mechanical stress and the local activation of infiltrated lymphocytes and macrophages. The non-invasive detection of aneurysm wall inflammation, using 18-fluorodeoxyglucose positron emission tomography (FDG-PET) might therefore provide valuable information on the extent of the disease and could clarify the role of mechanical stress on the propagation of aneurysm wall inflammation.

Study objective

Correlation of FDG uptake and in vitro aneurysm wall tensile strength. (primary objective). The effect of aneurysm sac depressurisation, after endovascular aneurysm repair, on aneurysm wall inflammation (secondary objective).

Study design

Observational case series (pilot).

Study burden and risks

Patients scheduled for conventional (open) or endovascular aneurysm repair are

admitted to the hospital the day before surgery. At that point all patients will be evaluated using FDG-PET/CT. Although intake of sugar-free liquids is permitted, glucose intake is restricted 6 hours prior to FDG-PET imaging. One hour after intravenous injection of 200-220 MBq FDG, whole body emission and transmission images will be acquired. To determine inflammation markers (e.g. CRP), blood and urine samples will be collected prior to the operation and again 6 weeks after surgery. For in vitro aneurysm wall tensile strength testing wall specimens will be harvested during conventional aneurysm repair. To study the influence of bloodpressure on aneurysm wall inflammation, a second FDG-PET/CT will be performed 6 weeks after the endovascular treatment of the aneurysm.

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 (open) or endovascular aneurysm repair.
2. Informed consent.

Exclusion criteria

1. Diabetes Mellitus Type 1 and 2
2. Ruptured abdominal aortic aneurysm.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-06-2007

Enrollment: 35

Type: Anticipated

Ethics review

Approved WMO

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
CCMO	NL17447.091.07