Visualization of occult endoleaks after endovascular aortic aneurysm repair (EVAR) using Vasovist - a pilot study

Published: 19-09-2006
Last updated: 14-05-2024

To visualize occult endoleaks in patients after endovascular abdominal aortic aneurysm repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON29761

Source
ToetsingOnline

Brief title
Vasovist endoleak study

Condition

- Aneurysms and artery dissections

Synonym
aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Schering,Schering bv (leverancier contrastmiddel)

Intervention

Keyword: delayed MR angiography, endoleak, endovascular abdominal aortic aneurysm repair, follow-up

Outcome measures

Primary outcome

Number of occult endoleaks only detected at late MR after positional change of

the patients

Endoleaks will be graded on a 5-point scale (no endoleak, possibly endoleak,

probably endoleak, definitely endoleak, not diagnostic).

Secondary outcome

Number of occult endoleaks detected by

- delayed CT

- dynamic MRA

- dynamic MRA + MRA delay 1

- MRA delay 2

- T1-w postcontrast spin echo images (delay 1)

- T1-w postcontrast spin echo images (delay 2)

• Number of endoleaks detected by

- static MRA (first-pass)

- MRA delay 1

- MRA delay 2

• Thrombus enhancement

• Change in reader confidence for the detection of endoleaks

Study description

Background summary

In patients after endovascular abdominal aortic aneurysm repair (EVAR), life-long follow-up with imaging techniques is necessary to measure aneurysm size and to detect endoleaks. After successful treatment, the aneurysm should shrink. The processes which take place inside endovascularly treated aneurysms are still unknown. If aneurysms do not shrink after endovascular treatment, this is attributed to endoleaks. However in the case of non-shrinkage in absence of endoleak, the etiology of the non-shrinkage is unclear. We hypothesize still an andoleak may
be present which is not visualized by conventional imaging techniques (either due to slow-flow or due to intermittent leakage, e.g. posture-dependency).

Study objective

To visualize occult endoleaks in patients after endovascular abdominal aortic aneurysm repair.

Study design

Single-center pilot study

Study burden and risks

Each patient is asked to undergo one additionalMRI-scan, which includes a break of half an hour. Normal risks and contraindications for MRI apply. The contrast agent Vasovist is based on the magnetic properties of gadolinium. However, contrary to normal standard gadolinium contrast agent in use for MRI, this compound binds to human serum albumin, which prolongs the halflife of retention in the intravascular space to 2 hours. The additional complaints expected from this drug are comparable to the standard contrast agent.

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

minmally 1 years after EVAR
in whom CTA demonstrated no decrease in outer diameter of the aneurysm
in whom no endoleak was detected on CTA
MR must be completed within 1 month after the CT examination.

Exclusion criteria

contraindications for MRI-examination
contraindication for use of contrast agent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2006
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	19-09-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL11974.041.06