Imaging of the aneurysmal wall using 7 Tesla MRI in unruptured intracranial aneurysms

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The main goal of this pilot study is to analyze if using the 7.0 Tesla MRI scanner potential markers predicting aneurysmal rupture (i.e thickness and enhancement of the aneurysmal wall) can be studied in IA patients.

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

Summary

ID

NL-OMON41401

Source
ToetsingOnline

Brief title
7T imaging of unruptured intracranial aneurysms

Condition

- Aneurysms and artery dissections

Synonym
intracranial aneurysms; vascular abnormality in the head

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 7 tesla MRI, intracranial aneurysm, rupture

Outcome measures

Primary outcome

To study whether the thickness and enhancement of the aneurysmal wall can be

studied in patients with unruptured IA using 7.0 Tesla MRI.

Secondary outcome

Secondary objective: to optimize the scanning protocol for visualization of

enhancement of aneurysmal wall

Tertiary objective: To study whether differences in the thickness and

enhancement of the aneurysmal wall exists between small unruptured aneurysms of

<= 7mm and large unruptured aneurysms >7mm in size.

Study description

Background summary

Most intracranial aneurysms are discovered after rupture. Rupture results in subarachnoid hemorrhage (SAH), which has a case fatality rate of 35%. With greater availability and higher accuracy of the imaging techniques, unruptured intracranial aneurysms(IA) are increasingly being discovered. These aneurysms may give rise to SAH in the near or distant future, but our abilities to predict which IA are going to rupture and when are limited. It is not rational to treat all IA, because treatment carries a risk of around 5% of complications leading to death or dependence on help for activities of daily living. Thus for a tailored approach markers predicting rupture in individual patients are urgently needed.
The thickness and enhancement of the aneurysmal wall may be related to a higher risk of rupture. Size is the most important known risk factor of rupture, but the conventional imaging can only visualize the vessel lumen which may lead to an underestimation of size. With the new technique of high-resolution 7.0 Tesla

Magnetic Resonance Imaging (MRI) scanner the circle of Willis can be studied in more detail.

Study objective

The main goal of this pilot study is to analyze if using the 7.0 Tesla MRI scanner potential markers predicting aneurysmal rupture (i.e thickness and enhancement of the aneurysmal wall) can be studied in IA patients.

Study design

This is an observational study.

Study burden and risks

This study will not have a direct benefit for the patients, but by participating in the study the patients will make an important contribution to the research on the cause of IA and on the cause of bleeding from such IA. Patients with contra indications for the 7.0 Tesla MRI will be excluded for this study. As known thus far there are no important side effects for the 7.0 Tesla MRI in patients without contra indications. The studies using 7.0 Tesla MRI performed thus far did not give any reason for concerns on the safety of this imaging technique. However, some patients experienced complaints of nausea and dizziness when walking too fast through the magnetic field. These complaints are temporarily and are not considered to be harmful. When the patients move slowly through the room with the scanner and when they are moved slowly into the scanner the chance that the patients experience these complaints will be diminished.
During scanning, they can experience light flashes or tingling. These experiences will disappear immediately after completion of the scan. The risks attributable to gadolinium are negligible since patients are excluded when they have previously experienced an allergic reaction to gadolinium or have a medical history of impaired renal function. Furthermore, an intravenous line will be placed to make administration of gadolinium during the scan possible. This might in certain cases result in minor pain, redness and swelling at the place of injection / place of the intravenous line.

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

Patients of age 18 years or older capable of giving consent with an unruptured intracranial aneurysm who either need surgical clipping or endovascular treatment to treat the aneurysm or are followed through the outpatient department with routine follow-up imaging. Patients are available for scanning before possible treatment takes place.

Exclusion criteria

Patients with an unruptured intracranial aneurysm who:
• are aged 18 years or younger
• are mentally or physically incapable of giving consent
• can not undergo MRI (claustrophobia, implants or metal objects in or around the body that can influence the scanning or can compromise the safety of the patient)
• have presence of a clip on or coils in another aneurysm
• have a fusiform, mycotic or traumatic unruptured aneurysm.
• are not able to understand Dutch or English written and/or spoken patient information
•Medical history of allergic reaction to gadolinium
•Patients with a medical history of impaired renal function (severe renal insufficiency, glomerular filtration rate (GFR) < 30 ml/min/1,73 m2; or nephrogenic systemic fibrosis/ nephrogenic fibrosing nephropathy (NSF/NFD)).

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):	07-07-2011
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2011
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-03-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-11-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	26-03-2015
Application type:	Amendment
Review commission:	METC NedMec

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	NL35277.041.11