Gadolinium-enhanced aneurysm wall imaging of unruptured intracranial aneurysms

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1. To assess the prevalence of gadolinium-enhancement of the aneurysm wall in patients with unruptured aneurysms2. To assess the relation between gadolinium-enhancement of the aneurysm wall and a. The use of anti-inflammatory drugs (including...

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

Summary

ID

NL-OMON41834

Source
ToetsingOnline

Brief title
LUMINA-study

Condition

- Aneurysms and artery dissections

Synonym
Unruptured intracranial aneurysm - protuberance of a blood vessel

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: Gadolinium, Intracranial aneurysm, Unruptured, Vessel wall imaging

Outcome measures

Primary outcome

The presence (present/absent) of gadolinium-enhancement of the aneurysm wall on

3 Tesla MR-angiography (MRA).

If evaluation of the first 15 patients results in the possibility of a

semi-quantitative outcome endpoint for contrast enhancement

(none/mild/severe/complete), we will discuss the use of this endpoint with the

entire study group.

Secondary outcome

Determinants of gadolinium-enhancement:

a. The use of anti-inflammatory drugs (including acetylsalicylic acid);

b. Hypertension;

c. The size of the aneurysm;

d. The relation with smoking.

Study description

Background summary

Rupture of an intracranial aneurysm results in aneurysmal subarachnoid hemorrhage (SAH). Currently, unruptured aneurysms can be treated with surgical clipping or endovascular coiling to prevent SAH, but both treatments carry a 5-15% risk of unfavorable outcome. Therefore, patients and their treating physicians have to weigh the balance between the risk of rupture and the risk of treatment complications. In general, small aneurysms with a low risk of

rupture are left untreated. However, most episodes of SAH come from small aneurysms, because small aneurysms are much more prevalent. Thus, additional treatment strategies with a low risk of complications are needed that can be used in patients with aneurysms with a low risk of rupture. A growing body of evidence suggests that aneurysm wall inflammation contributes to aneurysm growth and rupture. In patients with other vasculopathies such as intracranial atherosclerosis and vasculitis, 3 Tesla MRI vessel wall imaging can be used to detect sites with inflammation. Detection of aneurysm wall inflammation in-vivo would pave the way for a randomized controlled trial to investigate the effect of anti-inflammatory drugs on aneurysm growth and rupture. In this study, we will investigate the prevalence of gadolinium-enhancement of the aneurysm wall and its determinants (use of anti-inflammatory drugs, hypertension, aneurysm size and smoking behaviour) in patients with unruptured intracranial aneurysms. The overall aim of the proposed study is to develop a new, non-invasive medical treatment strategy that reduces the risk of rupture for patients with unruptured intracranial aneurysms. In the present study we will assess the prevalence of inflammation of the aneurysm wall and its determinants in patients with unruptured intracranial aneurysms.

Study objective

1. To assess the prevalence of gadolinium-enhancement of the aneurysm wall in patients with unruptured aneurysms

2. To assess the relation between gadolinium-enhancement of the aneurysm wall and
a. The use of anti-inflammatory drugs (including acetylsalicylic acid);
b. Hypertension;
c. The size of the aneurysm;
d. The relation with smoking.

Study design

The proposed study is a single-center, cross-sectional study.

Study burden and risks

The extent of burden and risks for participants of this study are minimal. The patients included in the proposed study regularly undergo 3 Tesla MRA or CTA as part of the clinical care for evaluation of possible growth of their unruptured aneurysm. For patients that are scheduled for MRA, the proposed study adds administration of gadolinium to the MRA-protocol for additional aneurysm wall imaging, which results in prolongation of the scan time of approximately 20 minutes. For patients that are scheduled for CTA, the proposed study adds an additional MRI with MRA and aneurysm wall imaging (scan duration of approximately 25 minutes). For patients that are not scheduled for MRI/CTA

(thus patients that are asked to visit the hospital for a study visit), participation in the proposed study will include an MRI with MRA and aneurysm wall imaging (scan duration of approximately 25 minutes). In addition, included patients have to complete a questionnaire on risk factors for aneurysm rupture and their use of medication, which will take approximately 30 minutes.

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

18 years or older.
Patient is diagnosed with one or more unruptured intracranial aneurysms confirmed on digital subtraction angiography (DSA), computed tomography angiography (CTA), or magnetic resonance angiography (MRA).

Informed consent signed by subject.

Exclusion criteria

Medical history of sever renal insufficiency: GFR<30ml/min/1.73m; nephrogenic systemic fibrosis / nephrogenic fibrosing nephropathy (NSF/NFD).
Gadolinium contrast allergy.
Pregnancy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2014
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	06-08-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	12-08-2015
Application type:	Amendment
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	NL48746.041.14

Study results

Date completed:	19-11-2015
Actual enrolment:	80