IMproving Risk PREdiction of Intracranial AneurysmS

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The primary aim of this study is to evaluate the relation between wall characteristics and recently detected aneurysm growth. The secondary aim is to investigate the relation between intraaneurysmal hemodynamics and wall characteristics.

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

Summary

ID

NL-OMON46878

Source
ToetsingOnline

Brief title
IMPRES

Condition

- Aneurysms and artery dissections

Synonym
Aneurysm, blood-filled balloon-like bulge in the wall of a blood vessel

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting TWIN

Intervention

Keyword: Intracranial aneurysms, prediction, rupture risk

Outcome measures

Primary outcome

The primary study parameters are wall thickness and wall enhancement.

Secondary outcome

Secondary study parameters are wall shear stress, qualitative flow

characterization, location and size of the aneurysm, and the patients age and

gender.

Study description

Background summary

Intracranial aneurysms are found in approximately 3% of the adult population. Due to an increased use of imaging, the number of incidentally found unruptured aneurysms grows. The optimal management of these aneurysms is still controversial. Aneurysms are mainly treated when they are in the posterior circulation or when they are larger than 7mm in diameter. However, most incidentally found aneurysms are small and a proportion of these do rupture. Therefore, better rupture risk predictors are necessary. It is hypothesized that characteristics of the aneurysm wall have a predictive value for growth, which is a surrogate outcome measure for rupture. Furthermore, it is thought that flow patterns play a major role in the adherence of inflammatory cells and the response of the endothelial cells to local inflammation.

Study objective

The primary aim of this study is to evaluate the relation between wall characteristics and recently detected aneurysm growth. The secondary aim is to investigate the relation between intraaneurysmal hemodynamics and wall characteristics.

Study design

This is a duo-center (AMC and UMCU), cross-sectional study. Wall thickness,

wall enhancement (related to inflammation), and flow patterns will be investigated using 3T/7T Magnetic Resonance Imaging (MRI). Univariate analysis will be performed to assess the association with recently detected aneurysm growth. For all statistically significantly associated parameters a multivariate logistic regression analysis will be performed to assess the independent contribution of all parameters to aneurysm growth.

During a single session, 80 patients will receive 3T/7T MRI without contrast agent to analyze the wall thickness, intraaneurysmal flow, and aneurysm geometry followed by 3T/7T MRI with a gadolinium-based contrast agent to depict aneurysm wall enhancement. The acquisition time will be approximately 60 minutes in total.

Study burden and risks

3T/7T MRI of all study parameters will be performed during a single session, with a total acquisition time of approximately 60 minutes. The risk of participation to this study is low. MRI is a safe imaging technique without radiation exposure. For imaging of the wall enhancement, gadolinium-based contrast agent will be administered. Side effects of the MRI contrast agent are rare and usually harmless. Patients will be screened for contra-indications for (7T) MRI and contrast agent. Patients participating in this study will receive additional imaging of the aneurysm. Besides this potential benefit, individual patients will not benefit directly from participation in this study. However, we expect this study to lead to a better identification of growing aneurysms, providing a better management of unruptured intracranial aneurysms.

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

Detected unruptured, untreated intracranial aneurysm
>18 years

Exclusion criteria

Standard contra-indications for MRI
- metallic implants, e.g. pacemaker
- Claustrophobia;Renal clearance <30ml/min (For contrast-agent administration).;Exclusion
criteria for 7T MRI (we can offer 3T MRI as an alternative):
Additional contraindications for ultra-high-field 7T MRI
- vascular implants such as stents, clips, coils, valves obtained from previous aneurysm
treatment

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):	28-10-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	26-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55523.018.15