Gadolinium-enhanced aneurysm wall imaging of unruptured intracranial aneurysms: a follow-up study

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Primary objective: To investigate if the presence of aneurysm wall enhancement predicts aneurysm instability in the long-term. Secondary objective: To investigate if the absence of aneurysm wall enhancement predicts aneurysm stability in the long...

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

Summary

ID

NL-OMON51762

Source
ToetsingOnline

Brief title
LUMINA-FU

Condition

- Aneurysms and artery dissections

Synonym
Unruptured intracranial aneurysm - protuberance of a blood vessel in the brain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Bayer,Bayer en de Nederlandse Hartstichting,de Nederlandse Hartstichting

Intervention

Keyword: aneurysm, brain, wall ehancement

Outcome measures

Primary outcome

Instability (growth or rupture)

Secondary outcome

Wall ehnancement in the long-term.

Study description

Background summary

Unruptured intracranial aneurysms (UIAs) have a prevalence of 3.2% in the general population. UIAs usually remain asymptomatic, but if they subsequently rupture there are often severe clinical consequences. In selected groups, the risk of rupture may be <1% per year. Those risks associated with the natural history have to be balanced against the well-known treatment-related mortality and morbidity in seeking to secure a UIA, as the overall treatment-associated mortality and morbidity ranges from 0.5% to 0.7% and 3% to 17%, respectively. Past and current studies have suggested that UIAs may be classified as presenting a high or low rupture risk based on their location and size. However, the majority of UIAs is small. Additionally, the impact of any management strategy on health-related quality of life or cognition remains poorly investigated. Clinical decision making thus mainly relies on general risk factors organized in prognostic scores, such as the PHASES score. The balance between risk and benefit makes the identification of a specific, individual-based marker for higher risk of rupture a valuable addition to therapeutic decision-making processes.

There is strong evidence to suggest that growing aneurysms are at higher risk of rupture. A systematic review of the literature reveals an estimation of a yearly growth probability of 3.85% (95% CI 3.4% to 4.3%) with a total follow-up of 7799 patient-years and 300 growth events observed in 3079 patients and 3855 UIAs. Several studies suggested that growing UIAs have an increased risk of rupture, hence follow-up imaging of untreated UIAs is recommended. However, guidelines from the American Heart Association and European Stroke Organization lack recommendations on which patients should be considered for follow-up imaging and at what time interval it should be performed.

Preliminary studies have demonstrated that aneurysmal wall enhancement (AWE), using high-resolution vessel wall MRI, is linked to aneurysm instability (i.e., ruptured, symptomatic, or growing over time). Indeed, recent cross-sectional studies that included both ruptured intracranial aneurysms and UIAs suggested that, on 3.0-T vessel wall MRI, circumferential AWE more frequently manifests in unstable (i.e., ruptured, symptomatic, or having a morphologic structure that changes over time) rather than in stable (i.e., incidental or non-evolving) intracranial aneurysms. Although the prevalence of circumferential AWE was over 80% in unstable intracranial aneurysms, reflecting a high sensitivity to determine unstable status, 30% of stable UIAs also presented this pattern, reflecting the low specificity of this finding. Have a personalized imaging-based UIA-risk prediction model would allow physicians to characterize aneurysms as appropriate for conservative management or requiring invasive treatment to prevent rupture.

We aim to evaluate the long-term prognostic value of aneurysm vessel wall imaging.

Study objective

Primary objective: To investigate if the presence of aneurysm wall enhancement predicts aneurysm instability in the long-term.

Secondary objective:
To investigate if the absence of aneurysm wall enhancement predicts aneurysm stability in the long term.
To investigate changes in in the extent of aneurysm wall enhancement in the long-term.

Study design

This will be a prognostic monocenter study.

Study burden and risks

The proposed study adds administration of gadolinium to the MRA-protocol for additional aneurysm wall imaging. The use of gadolinium is safe and painless and is often used in clinical practice. In rare cases the use of gadolinium can cause an allergic reaction. In this case, the radiology staff will handle according to the protocol of allergic reactions. The extent of burden and risks for participants of this study are estimated to be negligible.

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

- Subject carrying unruptured and untreated typical intracranial aneurysm
- Age > 18 years old,
- Subject was included in previous LUMINA study or 7T study in 2014/2015

Exclusion criteria

- Mycotic, fusiform-shaped, or dissecting intracranial aneurysm, intracranial aneurysm in relation with arteriovenous malformation.
- Failure to obtain informed consent.
- Cavernous or partially thrombosed unruptured intracranial aneurysm.
- Severely impaired renal function (eGFR <30 ml/min)

- MRI or contrast agent contra-indication
- Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2022
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2022
Application type:	First submission
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	NL80007.041.22

Study results

Results posted: 30-09-2024

First publication
30-09-2024