# 4D MR flow detection of hemodynamic predictors for aneurysm rupture

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Relate aneurysm hemodynamics to aneurysm configuration and growth to obtain insight in the hemodynamic pathophysiology of aneurysm growth in order to improve prediction of aneurysm rupture.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Cardiac and vascular disorders congenital |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON50060

**Source**
ToetsingOnline

**Brief title**
Flow@Aneurysm

### Condition

- Cardiac and vascular disorders congenital
- Aneurysms and artery dissections

**Synonym**
Aneurysm; local bulge of the artery wall

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Nederlands hartstichting

## Intervention

**Keyword:** Aneurysm, Flow, Hemodynamics, Rupture

## Outcome measures

### Primary outcome

Is it possible to visualize and quantify hemodynamics in an intracranial

aneurysm using 4D flow acquisition on 7 Tesla (7T) MRI. We will do this on the

basis of:

a. mean flux,

b. stroke volume,

c. type of blood flow in the aneurysm compared to the supplying vessel

### Secondary outcome

d. aneurysm size (length, width and neck size),

e. aneurysm growth over time

f. irregularity

# Study description

### Background summary

Growth and rupture of unruptured intracranial aneurysm (UIAs) is a multifactorial process with hemodynamic stress as important contributor. In the last years, hemodynamic parameters (such as pressure distribution and wall shear stress) have been introduced as a promising tool to improve the prediction of aneurysm rupture [1]. Currently it is difficult to predict rupture, which limits clinical decision making and patient counselling. For example; larger posterior circulation aneurysms have a high rupture risks that typically justifies intervention, but most instances of aneurysmal SAH are caused by rupture of a relatively low-risk small anterior circulation aneurysms as these small aneurysms outnumber aneurysms at other locations. Thus, we need better individual risk prediction for aneurysms to select those that will

rupture.

### Study objective

Relate aneurysm hemodynamics to aneurysm configuration and growth to obtain insight in the hemodynamic pathophysiology of aneurysm growth in order to improve prediction of aneurysm rupture.

### Study design

in a cohort of 40 patients with an unruptured and asymptomatic intracranial aneurysm of at least 4 mm, who come for their periodic clinical follow-up scan on the CE-labeled 3T MRI scanner, we will additionally make a 4D flow scan on the 7T MRI on the same day. Patients are included for a period of 12 months

### Study burden and risks

Subject does not need to come to the hospital extra, the additional scan takes about 10 minutes and in total (including patient on the scanner and away from the scanner) the scan will take a maximum of half an hour. The scan will not need to be reported. The additional scan is scheduled as soon as possible after the clinical scan. One of the researchers will guide the patient during the scan. No ionizing radiation is given. No contrast agent is given, and therefore no IV

## 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 with unruptured intracranial aneurysms larger than 4mm

### Exclusion criteria

Patients younger than 18 years old and patients who are pregnant

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-06-2021 |
| Enrollment: | 40 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Philips Achieva 7.0T |
| Registration: | No |

## Ethics review

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|---|---|
| Approved WMO Date: | 31-12-2020 |
| 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 | NL74775.041.20 |