

# Quantification of wall pulsations in intracranial aneurysms with 4D CTA: a pilot study.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON28607

### Source

Nationaal Trial Register

### Brief title

PulCerA

### Health condition

Unruptured intracranial Aneurysms.

## Sponsors and support

**Primary sponsor:** RadboudUMC

**Source(s) of monetary or material Support:** 1st line, (1e geldstroom), radiology department Radboud UMC

## Intervention

## Outcome measures

### Primary outcome

Cardiac-cycle related pulsatile motion of the intracranial aneurysm wall in individual aneurysms.

## Secondary outcome

-

## Study description

### Background summary

Rationale: Intracranial aneurysm (IA) wall motion is proposed to indicate locations with reduced stability. If reliable measurements of the pulsatility could be performed, increased pulsatile wall motion could be a valuable addition to the current rupture risk estimation. The magnitude of the pulsations is unknown, impeding the validation of IA pulsations. Therefore, a validated measurement of the IA pulsation is required.

Objective: Detecting and quantifying the cardiac cycle-related pulsatility of the intracranial aneurysm wall with 4D CTA.

Study design: Observational pilot study.

Study population: Adult patients admitted to the Radboud UMC for the follow-up of unruptured and untreated intracranial aneurysms.

Main study parameters/endpoints: Cardiac-cycle related pulsatile motion of the intracranial aneurysm wall.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: A radiation dose of approximately 3 mSv is added. This study contributes towards a refined rupture risk estimated in patients with unruptured and untreated aneurysms.

### Study objective

Pulsatile wall movement can be quantified with 4D CTA.

### Study design

In December and Januari, 15 patients are scanned with a 4D CTA scanner. These scans are analyzed in batches of 3 to 5 patients for the primary outcome. The data analysis is performed in Matlab, using a costum made algorithm.

### Intervention

-

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1. Adult patients with untreated and unruptured intracranial aneurysm(s).
2. Planned for a follow-up scan in the Radboud UMC
3. Informed consent.

### Exclusion criteria

1. Contra-indications for CT or contrast agent (pregnant, allergic to contrast agent)
2. Aged below 18 years or mentally incompetent.
3. Patients with impaired kidney function, at least eGFR  $<60$  ml/min/1.73m<sup>2</sup>;
4. Patients with treated aneurysm at similar height of the untreated and unruptured aneurysm

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control: N/A , unknown

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2020

Enrollment: 30

Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

Date: 22-09-2020

Application type: First submission

## 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
NTR-new	NL8936
Other	METC Arnhem-Nijmegen : 2020-6980

## Study results