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

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Detecting and quantifying the cardiac cycle-related pulsatility of the intracranial aneurysm wall with 4D CTA. Besides, the pulsating belbs will be differentiated from noise-induced pulsations.

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

Summary

ID

NL-OMON51180

Source ToetsingOnline

Brief title PulCerA

Condition

• Aneurysms and artery dissections

Synonym aneurysm of brainvessels, Intracranial aneurysm

Research involving Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

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Intervention

Keyword: Cerebral aneurysm, ECG-gated 4D CTA, pulsations, vessel wall stability

Outcome measures

Primary outcome

The presence of cardiac-cycle related pulsatile blebs of the intracranial

aneurysm wall.

Secondary outcome

quantification of the pulsatile behaviour of the entire aneurysm dome and the

vascular tree motion. Comparison between two differenct CT scanners.

Study description

Background summary

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.

Study objective

Detecting and quantifying the cardiac cycle-related pulsatility of the intracranial aneurysm wall with 4D CTA. Besides, the pulsating belbs will be differentiated from noise-induced pulsations.

Study design

Observational pilot study.

Study burden and risks

A radiation dose of 3 mSv is added and there is a risk for side effects of the contrast agent. This study contributes towards a refined rupture risk estimated in patients with unruptured and untreated aneurysms.

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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

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

Exclusion criteria

1. Contra-indications for CT or contrast agent (pregnant, patients with an allergic reaction to contrast agent or patients with Kahler's or Waldenstrom's syndrom)

- 2. Aged below 18 years or mentally incompetent.
- 3. Patients with impaired kidney function, at least eGFR <60 ml/min/1.73m2;
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4. Patients with coiled aneurysms at the same height as the untreated aneurysm.

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):	08-12-2020
Enrollment:	30
Туре:	Actual

Ethics review

24-11-2020
First submission
CMO regio Arnhem-Nijmegen (Nijmegen)
12-05-2021
Amendment
CMO regio Arnhem-Nijmegen (Nijmegen)

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
ССМО	NL75245.091.20
Other	NL8936

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