Comparison of subtraction computed tomography angiography, contrast enhanced magnetic resonance angiography and digital subtraction angiography as follow-up imaging modalities in flow diverter treatment for intracranial aneurysms

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON47976

Source
ToetsingOnline

Brief title
sCTA, ceMRA vs DSA after flow diverter treatment

Condition

- Central nervous system vascular disorders

Synonym
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

Intervention

Keyword: ceMRA, Flow diverter, Follow-up, sCTA

Outcome measures

Primary outcome

The main study endpoint is the number of false negative findings for aneurysm occlusion as measured by sCTA and ceMRA according to modified Raymond-Roy classification.

Secondary outcome

The secondary study endpoints include positive and negative predictive value, sensitivity, specificity for complete aneurysm occlusion; degree of aneurysm occlusion, parent artery patency, device deployment, wall apposition and neck coverage as measured by sCTA and ceMRA; complications related to diagnostic methods and interreader agreement for all the imaging techniques.

Study description

Background summary

Flow diversion (FD) is a relatively new endovascular treatment strategy which focuses on parent vessel reconstruction and occlusion of the aneurysm. Digital subtraction angiography (DSA) is considered the gold standard for the evaluation of the degree of aneurysms occlusion in treated patients. However, this diagnostic method is invasive with a risk of thromboembolic and contrast media associated complications. In addition, it does not depict the

surroundings of the aneurysm. There are some case series on non-invasive diagnostic methods such as subtraction computed tomography angiography (sCTA) and contrast enhanced magnetic resonance angiography (ceMRA), though the reliability of sCTA or ceMRA is not known.
Recently, a pilot study was conducted in our centre to explore the diagnostic accuracy and safety of sCTA after FD treatment in non-occluded aneurysms in comparison with DSA. Preliminary pilot data of this study are promising however sCTA requires validation as follow-up modality as diagnostic tool. In addition, various studies report the use of ceMRA as follow-up imaging modality.

Study objective

The main objective of this study is to explore the accuracy of sCTA and ceMRA compared to DSA in the diagnosis of complete aneurysm occlusion in patients treated with a FD stent. In addition, we will look at accuracy of sCTA and ceMRA in visualisation of aneurysm occlusion grade, parent vessel patency and the position of a FD stent, and we will assess the safety of both methods.

Study design

Single centre prospective cohort study, patients will be enrolled on consecutive basis.

Study burden and risks

Patients will undergo additional sCTA next to DSA and ceMRA or additional sCTA and ceMRA next to DSA. We will attempt to combine DSA, ceMRA and sCTA on the same day. The contrast used for sCTA is the same as for DSA and rarely related to adverse reactions. We will not include patients at risk of contrast-induced nephropathy and patients who have recently undergone liver transplantation in this study. The total amount of additional radiation due to participation will be 2,4 mSv.

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

aneurysm treated with a flow diverter; 18 years or older

Exclusion criteria

known contra-indications to ceMRA, sCTA or DSA, renal insufficiency

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-09-2019
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	26-02-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-08-2019
Application type:	Amendment
Review commission:	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

ID: 24710
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68375.091.18
OMON	NL-OMON24710