Follow-up of intracranial aneurysms treated with the Surpass flow diverter: comparison of subtraction CTA and DSA. Part I: a prospective case cohort study

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Primary objective: - To determine the accuracy of sCTA compared to DSA in the visualisation of the degree of occlusion in the FU of intracranial aneurysms treated with Surpass. Secondary objectives:-To determine the accuracy of sCTA compared to DSA…

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

Summary

ID

NL-OMON42510

Source
ToetsingOnline

Brief title
Follow-up Surpass: sCTA vs DSA. Part I.

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
vascular ectasia, vessel wall protrusion

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: subsidieaanvraag in verwerking

Intervention

Keyword: DSA, Flow diverter, subtraction CTA, Surpass

Outcome measures

Primary outcome

The main parameter is the difference in the degree of aneurysm occlusion. This

will be measured by:

- Calculation of the aneurysm volume with residual contrast filling.

- The Raymond classification.

Secondary outcome

Secondary parameters:

The patency of the parent vessel will be measured on a 4-point scale.

Complications will be registered.

Study description

Background summary

Using flow diverters (stent-like implants that divert the flow from the aneurysm sac) to treat unruptured intracranial aneurysms is increasingly accepted as the treatment of choice. Nowadays, the gold standard for radiological follow*up (FU) to evaluate the degree of occlusion of aneurysms is digital subtraction angiography (DSA). Some non-invasive diagnostic methods have also been described, but there is a lack of evidence about their reliability.
Subtraction CT angiography (sCTA) is a promising non-invasive technique with an accurate spatial resolution that could theoretically provide the same information as DSA.
We will perform a sCTA and a DSA, the latter of which is the standard

radiological FU, and will then compare the accuracy of the two methods in terms of the visualisation of the degree of occlusion of an aneurysm. The first radiological FU will be scheduled for 1 month after treatment with the Surpass flow diverter device (Surpass).

Study objective

Primary objective:
- To determine the accuracy of sCTA compared to DSA in the visualisation of the degree of occlusion in the FU of intracranial aneurysms treated with Surpass.

Secondary objectives:
-To determine the accuracy of sCTA compared to DSA in the visualisation of the patency of the parent vessels, and the correct deployment, position and apposition of the Surpass.
-To assess the complications related to the two diagnostic methods.

Study design

Single centre, prospective case cohort study.

Study burden and risks

In addition to the standard FU DSA, patients will undergo a sCTA 1 month after the implantation of the Surpass. This will not lead to a longer admission, as we will schedule both studies on the same day. This may mean that a patient has to stay in the hospital for a slightly longer time (approximately 1 hour). As sCTA is a non-invasive technique, with side-effects that only very rarely arise as a result of the administration of the contrast agent, any additional risks are estimated to be nearly zero.
As it is still unclear when aneurysms precisely occlude after implantation of the Surpass, we will schedule the first radiological FU 1 month thereafter. If we obtain evidence about actual occlusion times, we may be able to discharge patients from further FU earlier. This would have important financial and patient-related emotional consequences.
An extra 50cc of contrast agent will be administered in addition to the standard care DSA. Patients at risk of contrast-induced nephropathy will be excluded from participation. Adverse reactions related to the use of the contrast agent (Xenetix) are generally mild to moderate, and transient. The adverse reactions most commonly reported are feeling of warmth, pain and oedema at the injection site. The hypersensitivity reactions are usually immediate (during the injection or over the hour following the start of the injection) or sometimes delayed (one hour to several days after the injection).
The total amount of extra radiation that patients will receive at each sCTA is 2.6 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

adults (age: 18 to 80) with an unruptured intracranial aneurysm treated with Surpass.

Exclusion criteria

subarachnoid hemorrhage, earlier coiled aneurysm, allergy (hypersensitivity to iobitridol, history of major immediate or delayed skin reaction to Iobitridol injection) or contraindication to contrast agent (manifest thyrotoxicosis, recent treatment with intravenous interleukin 2), use of nephrotoxic medicines (aminoglycosides, organoplatinum compounds, high doses of methotrexate, pentamidine, foscarnet, aciclovir, ganciclovir, valaciclovir, adefovir, cidofovir, tenofovir, vancomycin, amphotericin B, immunosuppressants such as ciclosporine or tacrolimus, ifosfamide), contraindication to CT scan, renal insufficiency, pregnancy, and age

<18 years.

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):	30-11-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-02-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL54066.091.15