Flow diverter (surpass) for unruptured intracranial aneurysms: A prospective single-center study in 37 patients - long-term follow-up

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The primary objective is to evaluate long-term reperfusion rate, neurological outcome and quality of life in patients with unruptured intracranial aneurysm treated with the Surpass Flow Diverter (Surpass; Stryker Neurovascular, Fremont, CA).

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

Summary

ID

NL-OMON49122

Source
ToetsingOnline

Brief title
Long-term outcome after Surpass flow diverter

Condition

- Aneurysms and artery dissections

Synonym
cerebral aneurysms, vascular ectasia

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: Aneurysm, Flow diverter, Surpass

Outcome measures

Primary outcome

Reperfusion on DSA.

Secondary outcome

Quality of life compared to the standard population by SF-36

Study description

Background summary

Intracranial aneurysms (IA) are mostly saccular lesions of the vessel wall in the large vessels obtaining blood supply to the brain. IA are mostly located on vessel bifurcations and are predominantly located in the anterior circulation. IA can be found in approximately 1-2 % of the population. The IA itself is normally asymptomatic and is often an incidental finding, but still, a ruptured IA is the reason for 80-85 % of symptomatic subarachnoid hemorrhage (SAH). SAH is a dangerous disease accompanied by high morbidity. There are several risk factors determining the risk for IA rupture and a consecutive SAH as smoking, hypertension, familiar disposition, polycystic kidney, Age, hypertension, IA morphology, and multiple aneurysms. Depending on the total risk profile of a patient the Decision to treat or not to treat is done. There are multiple treating options for IA and nowadays endovascular treatment became the most common modality of treatment compared to surgical clipping. Nevertheless, endovascular coiling carries a high rate for reperfusion, aneurysms growth and is sometimes not doable without the risk for periprocedural ischemia.
The Surpass Flow Diverter (Surpass; Stryker Neurovascular, Fremont, CA) is a flow diverter for the reconstruction of the parent artery and aneurysm occlusion. The implant maintains a high pore density, uniform across the aneurysm neck, and is unaffected by the diameter of the parent artery. As implants with various diameters and lengths are available, 1 single implant is sufficient to treat the target aneurysm(s) and parent artery. The feasibility and safety of the Surpass were already described from our group in 2013 in a group of 37 patients with unruptured intracranial aneurysms, a good outcome in a 7-month follow-up was described.

Still, the biggest issue in endovascular treatment remains reperfusion and the risk for retreatment, therefor long-term outcome data is crucial.
For this purpose, we would like to investigate the long-term follow-up (5-year) of the previously described patient population with subtraction CT-angiography and clinical outcome measures to evaluate if the Surpass can reduce the high reperfusion rate of endovascular treated aneurysms.

Study objective

The primary objective is to evaluate long-term reperfusion rate, neurological outcome and quality of life in patients with unruptured intracranial aneurysm treated with the Surpass Flow Diverter (Surpass; Stryker Neurovascular, Fremont, CA).

Study design

The 37 patients who received a Surpass Flow Diverter (Surpass; Stryker Neurovascular, Fremont, CA) will be contacted if they want to participate in the long term follow-up.
Patients will undergo the DSA. On the same day SF-36 questionnaire will be taken and the results of the DSA will be discussed.

Study burden and risks

DSA is currently the golden standard for flow diverter treatment. The radiation dose is 3.0 mSv. This technique is rather safe with a low chance of complications. The most common complications are mild, such as puncture site hematoma and contrast reaction. The chance of major complications is very low. There is no standard protocol for long term follow-up of patients treated with flow diversion, nevertheless, possible reperfusion would put the patient at risk for subarachnoid hemorrhage. Therefore long-term follow up with DSA is justified.

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

Cerebral aneurysm treated with surpass flow-diverter >5 years ago

Exclusion criteria

no informed consent, contrast agent reaction, renal insufficiency

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-04-2021
Enrollment:	37
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2020
Application type:	First submission
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	NL70183.091.19