Cohort study for the treatment of unruptured intracranial aneurysms with flow diverters

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The main hypothesis of this study is that flow diverter is a safe and sustainable alternative to standard treatment for internal carotid artery aneurysms with unfavorable configuration.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24360

Bron
NTR

Verkorte titel
CATRIF

Aandoening

Intracranial aneurysm of internal carotid artery

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Innovatiefonds Zorgverzekeraars, Stryker

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is efficacy and safety of treatment with FD. Efficacy is defined as

aneurysm occlusion rate according to modified Raymond Roy occlusion classification on angiography performed 18 months after intervention. Safety is defined as change in dependence for activities of daily living (mRS) at 18 months after intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Intracranial aneurysms are common disorder affecting around 3% of the population. The treatment of ruptured and unruptured aneurysms usually consists of open surgical clipping or endovascular technique. Endovascular treatment such as coiling is generally considered safer than clipping, however, the technique has some limitations. Flow diversion is a new endovascular treatment strategy which focuses on parent vessel reconstruction and occlusion of the aneurysm. Despite encouraging results, lack of direct comparison between different treatment strategies and relatively high costs of the devices hinder the implementation of flow diverters as standard care for complex unruptured intracranial aneurysms.
Objective: The main objective of this study is to establish efficacy and safety of treatment with flow diverter for unruptured intracranial aneurysms in comparison to current standard care treatment. The secondary objectives include the assessment of potential effect of flow diverter treatment on functional outcome and a cost effectiveness analysis.
Study design: multicentre prospective cohort study.
Study population: patients with unruptured intracranial aneurysm of internal carotid artery, ≥18 years.
Intervention: this is an observational study where all the patients will receive standard care treatment. This includes flow diverter placement, microsurgical clipping, endovascular coiling with or without stenting and parent vessel occlusion with or without bypass.
Main study parameters/endpoints: the main study parameters are the occlusion rate of the aneurysm graded with modified Raymond Roy classification and change in dependence for activities of daily living at 18 months after intervention.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: considering the observational nature of the study no additional risks associated with participation are expected. The standardised questionnaires for all participating patients, telephone assessment of modified Rankin scale and assessment according to National Institutes of Health Stroke Scale are the only burdens of this study.

Doel van het onderzoek

The main hypothesis of this study is that flow diverter is a safe and sustainable alternative to standard treatment for internal carotid artery aneurysms with unfavorable configuration.

Onderzoeksopzet

3, 6, 12 and 18 months

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Suitability for FD treatment or alternative treatment will be identified according to the following inclusion criteria:
- unruptured intracranial aneurysm of internal carotid artery;
- unfavourable dome neck configuration (≤2), or neck ≥4 mm, or maximum aneurysm diameter ≥10 mm; or tandem aneurysms with any configuration; multisegmental disease;
- ≥18 years;
- modified Rankin Scale (mRS) ≤2;
- patients willing to provide written informed consent and comply with follow up requirements.
Patients eligible for FD but treated otherwise in the Radboudumc and patients eligible for this study and treated with FD in other centres should also be included in the study. A registry will be kept of patients treated with FD who did not meet the inclusion criteria for this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- intracranial hemorrhage within 30 days;
- presence of untreated ruptured intracranial aneurysm;
- ≥1 intracranial aneurysm except the target one which requires treatment within 12 months;

- contra-indication for dual antiplatelet therapy;
- known allergy or inadequate response to aspirin, heparin, clopidogrel, ticagrelor or prasugrel, other anti-platelet or P2Y12 agents or to general anesthesia (platelet reactivity will be assessed prior to the inclusion in patients who require anti-platelet or P2Y12 agents following the treatment);
- bifurcation aneurysm (e.g. pcom aneurysm with fetal or intermediate configuration where pcom cannot be occluded);
- immunosuppressive disease;
- active infectious disease (e.g. endocarditis, meningitis);
- platelet count < 100 x 103 cells/mm3 or known platelet dysfunction at time of enrollment;
- female of child-bearing potential who are unable to take adequate contraceptive precautions, are known to be pregnant, or are currently breastfeeding an infant;
- intracranial aneurysm correlating to arteriovenous malformation, dissecting aneurysms;
- patient with another unrelated intracranial disease and patients with any type of malignancy;
- major surgery within previous 30 days or planned in the next 120 days after enrolment;
- patient with a periprocedural International Normalized Ratio (INR)≥ 1.5;
- patient with any condition that, in the opinion of the treating physician, would place the participant at a high risk of embolic stroke or with any medical co-morbidity likely to affect the outcome (e.g. pulmonary disease, uncontrolled diabetes, protrombotic conditions, e.g. factor 5 Leiden);
- patient with a life threatening allergy to iodinated contrast media (patients with itching or rash as a reaction to contrast can be included if properly prophylactically treated);
- patient who is currently participating in another clinical research study involving an investigational product;
- stenting, angioplasty, or endarterectomy of an extracranial (carotid or vertebral artery) or intracranial artery within 30 days prior to the treatment date;
- unstable neurological deficit (i.e. worsening or improvement of clinical condition in the last 30 days unrelated to the aneurysm);
- patient who has participated in a drug study within the last 30 days;
- inability to understand the study or history of non-compliance with medical advice;
- patient who has had a previous intracranial procedure associated with the target aneurysm such that access and placement of an investigational device would be compromised.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-05-2019
Aantal proefpersonen:	83
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-05-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7722
CCMO	NL2017-3679

Resultaten