Minimal invasive follow up after flow diversion: 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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Follow-up imaging with sCTA or ceMRA could completely substitute conventional DSA in assessment of aneurysm occlusion grade and parent vessel patency after treatment with flow diverter

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

Samenvatting

ID

NL-OMON24710

Bron
NTR

Verkorte titel
MINIFLOW

Aandoening

Intracranial aneurysms

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Public

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of false negative findings for aneurysm occlusion as measured by sCTA and ceMRA. This will be assessed according to modified Raymond-Roy (mRR) classification.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.
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 population: adult patients treated with a FD who are planned to receive imaging follow-up with DSA and ceMRA.
Intervention: patients who are planned for DSA and ceMRA will undergo additional sCTA.
Main study parameters/endpoints: 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. 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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: patients will undergo additional sCTA next to DSA and ceMRA. 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.

Doel van het onderzoek

Follow-up imaging with sCTA or ceMRA could completely substitute conventional DSA in assessment of aneurysm occlusion grade and parent vessel patency after treatment with flow diverter

Onderzoeksopzet

All imaging modalities will be performed within one day.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the inclusion criteria as stated below:
- Aneurysm treated with a FD;
- ≥18 years;
- patients willing to provide written informed consent and comply with follow up requirements.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Known allergy (hypersensitivity or history of major immediate or delayed skin reaction to injection) or contraindication to the contrast agent Iomeron (manifest thyrotoxicosis, recent treatment with intravenous interleukin 2) or Dotarem;
- Use of nephrotoxic medicines (aminoglycosides, organoplatimun compounds, high doses of methotrexate, pentamidine, foscarnet, acyclovir, ganciclovir, valaciclovir, adefovir, cidofovir, tenofovir, vancomycin, amphotericin B, immunosuppressants such as cyclosporine or tacrolimus, isosfamide);
- Renal insufficiency (MDRD < 60 mL/min/1,73 m2);
- Patient who is currently participating in another clinical research study which might be influenced by the additional imaging investigations;
- Patients with a contraindication for MRA (e.g. metallic implants such as a pacemaker) or a metal clip in proximity to the studied aneurysm will only receive sCTA and DSA;
- Female of child-bearing potential who are known to be pregnant.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-06-2019
Aantal proefpersonen:	40
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:	23-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47976
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7893
CCMO	NL68375.091.18
OMON	NL-OMON47976

Resultaten