Invasive and non-invasive intracranial Flow velocity measurements in patients with UNruptured IntraCranial Aneurysms

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

Summary

ID

NL-OMON31258

Source
ToetsingOnline

Brief title
Flow UNICA

Condition

- Central nervous system vascular disorders

Synonym
balloonlike dilatation of cerebral bloodvessels, intracranial aneurysms

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Volcano Corporation (zie G1),Volcano Corporation sponsort in natura;5-20 ComboWire systems a 1500 euro/stuk

Intervention

Keyword: diagnostics, hemodynamics, intracranial aneurysms

Outcome measures

Primary outcome

Primary study parameters:

- measurement of flow velocities (in cm/s) in blood vessels proximal and distal of intracranial aneurysms as well as within the aneurysms. Flow velocities will be derived from invasive endovascular measurements using the ComboWire® and from non-invasive 4D phase-contrast MRA measurements.

- measurements of pressure (mmHg) in blood vessels surrounding intracranial aneurysms and within the aneurysm, using ComboWire®.

Primary outcome:

- Comparisons of flow velocity measurements in individual patients between invasive and non-invasive techniques to assess the accuracy of 4D phase-contrast MRA in measuring flow velocity.

Secondary outcome

Secondary study parameters:

- Measurement of the aneurysm wall displacement on 3DRA and 4D MRA images.

- Visual scores and quantative measurements of aneurysm morphology by two neuroradiologists based on 3DRA imaging and Maximum Intensity Projection (MIP) MRA images.

Secondary outcome:

- The construction of a computational model of aneurysm wall elasticity based

on pressure measurements and aneurysm wall distensibility.

- The determination of a relation between aneurysm morphology and its local

flow velocity and pressure.

- Modelling of local hemodynamics of intracranial aneurysms.

Study description

Background summary

Intracranial aneurysms are relatively common in the general population and can lead to moderate to severe disease when ruptured. Treatment of an unruptured aneurysm may be necessary dependent on the risk of rupture. Risk assessment is currently based on morphology and size of the aneurysm, but the predictive value of these characteristics is limited. Hemodynamic stress is considered to be one of the most important contributing factors to aneurysmal growth and rupture. Hemodynamic profiles have been predicted using computated models, but are dependent on several assumptions. Developing possibilities to accurately measure local hemodynamics in adjacent vessels and within the aneurysm, preferable non-invasively, will contribute to a better understanding and better assessment of risk of rupture of an intracranial aneurysm.

Study objective

The primary aim of this project is to compare measurements of flow velocity in parent and side branch vessels of intracranial aneurysms of ComboWire® with 4D phase-contrast MRA. We will assess the usefulness and accuracy of the 4D MRA for this aim. Measurements will be analyzed based on simple mechanic models and related to the functional regulation of the cerebral circulation. The secondary aim is to assess aneurysm wall elasticity using pressure measurements in vessels adjacent to and within intracranial aneurysms obtained by the ComboWire® and visualized vessel wall distension on MRA/ 3-dimentional Rotational Angiography (3DRA). The geometry and ComboWire® data may lead to more detailed theoretic models of local flow and pressure distribution in adjacent vessels and within the aneurysm.

Study design

A single-centre, prospective observational Pilot study.

Study burden and risks

Patients undergo an extra MRI-scan, which takes 30 minutes and poses no additional risk to the patient. During the endovascular treatment procedure the ComboWire® is used instead of the standard microguidewire, which has comparable characteristics but prolongs the procedure with 25 minutes, of which a maximum of 10 minutes extra fluoroscopy time. Patients with unruptured intracranial aneurysms may benefit from this study in the future. We expect this study to lead to a better identification of the *vulnerable aneurysm*, providing a better indication for preventive treatment.

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

- Patients with untreated unruptured aneurysms in or near the circle of Willis, found incidentally, in screening populations or in patients with multiple aneurysms
- Planned for endovascular treatment at the AMC
- Age 18- 70 yrs
- Written informed consent

Exclusion criteria

contrast allergy, impared renal function, contra-indications for MRI (pacemaker, claustrofobia, etc.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL18748.018.07