Safety and feasibility of absolute cerebral flow and microvascular resistance measurements by thermodilution using the PressurewireX

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This is a safety and feasibility study to assess the technical use of a pressure guidewire and monorail infusion catheter to measure intracranial intra-arterial pressure and absolute flow.

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

Summary

ID

NL-OMON57118

Source
ToetsingOnline

Brief title
Evaluation of the cerebral microcirculation

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cerebral perfusion, Microcirculation dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endovascular treatment, Microcirculation, Neurovascular

Outcome measures

Primary outcome

Main parameters of interest are intracranial intra-arterial pressure, flow and resistance measurements of the left and right internal carotid, middle cerebral and vertebral arteries. Procedural safety outcomes will be documented.

Secondary outcome

The reproducibility (first vs. second measurement, and right vs. left), the influence of a different infusion rates of saline (low vs. high rate), and the influence of sensor position (distal vs. proximal) will be evaluated by linear regression analysis and with Bland-Altman plots. Hemodynamic data will be reported per case.

Study description

Background summary

In the emerging neurovascular field there is a need for valid intracranial intra-arterial pressure, flow and resistance measurements to guide treatment decisions in the setting of both ischemic and hemorrhagic stroke and to perform research on development of new devices for neurovascular interventions. However, studies on evaluation of these measurements are lacking as opposed to the field of cardiology in which these techniques have been well established.

Study objective

This is a safety and feasibility study to assess the technical use of a pressure guidewire and monorail infusion catheter to measure intracranial

intra-arterial pressure and absolute flow.

Study design

Single center prospective cohort study

Study burden and risks

The patients will undergo the study procedure in the setting of an already planned DSA. The known risks associated with a regular DSA examination also apply to the use of the study wire and catheter (low risk of an inguinal hematoma and a very low risk of vascular damage such as dissection, occlusion and perforation). Moreover, the advantage of both the Rayflow catheter and the PressurewireX is the possibility of interchanging these with the guidewires and catheters already available on the market for neurovascular assessment. Intracranial manoeuvring is hereby very limited and only considers the introduction of the wire over a segment of approximately 3 cm intracranially into the vessel of interest. Since the route to the vessel of interest has already been obtained by manoeuvring with the known standard available guide wires and catheters during the regular workup DSA and the overall risk of serious complications is already very low, the additional risk of complications seen during/after a regular DSA as a result of the research intervention is considered to be negligible. The evaluation of the microcirculation opens a new door to the evaluation of various syndromes (microcirculation dysfunction after a cerebral infarction, vasculitis, stenosis) but also provides prognostic values and can contribute to direct evaluation of therapy effect during angiography (vascular spasm, microcirculation dysfunction after an ischemic stroke).

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

- Age 18 years or older
- Scheduled for diagnostic digital subtraction angiography (for the indication of Cerebral aneurysm, Tinnitus, Vasculitis, Follow-up after earlier embolization or neurosurgery) undergoing complete work-up of intracranial vessels (injection of at least left and right internal carotid artery)
- Written informed consent obtained

Exclusion criteria

- Any previous stroke or known neurological disorder associated with permanent structural brain abnormalities
- An untreated arteriovenous malformation in the anterior cerebral circulation
- Known history of:
o connective tissue disease
o significant stenosis of the common or internal carotid artery
o dissection in the internal carotid artery
- Hypercoagulability
- Physical or psychiatric condition making it for the patient impossible or uncomfortable to lay still during the procedure
- Visual pathology assessed during the diagnostic work-up that could interfere with the measurements.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	PressurewireX
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	25-11-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL84877.078.24