Transcranial Doppler (TCD) versus Computed Tomography Angiography (CTA) for the detection of cerebral vasospasm after subarachnoid hemorrhage

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Assessment of the diagnostic accuracy of CTA for the detection of vasospasm after SAH in comparison to TCD.

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

Summary

ID

NL-OMON40069

Source
ToetsingOnline

Brief title
TCD versus CT-A for detection of vasospasm after SAH.

Condition

- Central nervous system vascular disorders

Synonym
Bleeding in the subarachnoid space, Subarachnoid hemorrhage

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: -aneurysmal subarachnoid hemorrhage, -cerebral vasospasms, -diagnostic imaging

Outcome measures

Primary outcome

Accuracy of vasospasm detection.

Secondary outcome

Ischemic lesions on the brain MRI scan after 6 months

Study description

Background summary

Aneurysmal subarachnoid hemorrhage is caused by the rupture of an intracranial arterial aneurysm. It is a serious medical and life-threathening condition: one-third of the patients dies before reaching the hospital, one-third dies within the hospital of is severely disabled after discharge and one-third has no or minimal neurological deficits. Closure of the aneurysm is the treatment in the acute phase, to prevent rebleeding. The aneurysm can be closed by surgery (clipping of the aneurysm) or by endovascular coiling. During the first 3 weeks of an subarachnoid hemorrhage, several complications can occur, such as cerebral vasospasm. Vasospasm develop due to the blood in the subarachnoid spacce, and can lead to ischemic strokes due to insufficient cerebral blood flow. It is of importance to detect cerebral vasospasm in an early phase to prevent secondary ischemia.
The detection method of clinically relevant cerebral vasospasm is a matter of debate. A gold standard is a conventional angiography (DSA), however, the DSA is an invasive procedure and carries a 1-2% of complication risk. Currently, transcranial doppler (TCD) is often used to detect vasospasm. TCD is a non-invasive way to detect vasospasm and can be performed at patient bedside. The major disadvantages of TCD are that only a small part of the intracranial vasculature can be measured and that vasospasm found on TCD were often not clinically symptomatic. Moreover TCD is a time-consuming technique and the

quality of the results is dependent of the experience of the investigator.
There are studies that demonstrate that CT-angiography (CT-A) reliably detect vasospasm compared to DSA. The advantage of CT-A is that during the same CT scan the brain parenchyma can also be visualised and cerebral ischemia can be detected. The disadvantage of this technique is is use of intravenous iodine contrast and the radiation exposure of the CT scan. A recent national guideline in the Netherlands does not state which technique should be used to detect vasospasm. A comparison of CT-A and TCD is therefore needed to reveal which diagnostic method is the best way to detect vasopasm

Study objective

Assessment of the diagnostic accuracy of CTA for the detection of vasospasm after SAH in comparison to TCD.

Study design

This study is an observation pilot study in which prospectively consecutive patients with a subarachnoid hemorrhage are included. All patients are screened with TCD 2-3 times a week for vasospasm, according to the local management guidelines. Besides TCD, a CT-A scans are made for each patient on day 5 and 10 and in case of clinical deterioration. The results of TCD and CTA are compared and linked to clinical symptoms. In case of clinically symptomatic vasospasm, patients are treated according to a pre-defined protocol which is documenten in the local management guidelines. After finishing the pilot studies, we are planning to set-up a large scale cost-effectiveness study in order to investigate which method is most efficient.

Study burden and risks

By participation, the patients receive two additional CT-A scans to detect vasospasm. This means that patients have to be transported from the ward or intensive care unit (ICU) to the radiology department and have to be transferred from bed to the CT scan and vice-versa. As headache is a frequent complaint of patients with subarachnoid hemorrhage, this additional scan can be an extra burden for the patient, although all patients receive adequate painmedication. The same accounts also for transportation to the neurophysiology department, but sometimes TCD is done at the bedside of the patient on the ICU.
The CT-A scan carries a risk of contrast nephropathy due to the iodine containing contrast. However, the renal function is carefully monitored during the hospitalization.
The CT-A scans give also an extra radiation exposure to the patients, the cumulative dose is, however, low. The possible advantage of a better vasospasm detection outweigh the very small risks of these extra radioation exposure.

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 aneurysmal subarachnoid hemorrhage who can be included within 4 days after onset the subarachnoid hemorrhage
Age > 18 years
Written informed consent from the patient or next of a kin

Exclusion criteria

Moribund patients, in which no further treatment is considered.
Renal insufficiency, defined as an estimated glomerular filtration rate of < 60 ml/min/1.73 m2.
Known allergy against iodine contrast.

Treatment with metformine.
Morbus Kahler / M. Waldenstrom
Myasthenia gravis
Pheochromocytoma
Mastocytosis
Thyroid cancer
Planned thyroid scan

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-09-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20699
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41458.042.12
OMON	NL-OMON20699