Transcranial doppler And CTangiography for Investigating Cerebral vasospasm in Subarachnoid hemorrhage study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20699

Source
Nationaal Trial Register

Brief title
TACTICS

Health condition

Subarachnoid hemorrhage. Cerebral vasospasm

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Sensitivity and specificity.

Secondary outcome

Prediction of clinically relevant vasospasm.

Study description

Background summary

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 objective

Comparison of CT-angiography and Transcranial doppler for the detection of cerebral vasospasm after aneurysmal subarachnoid hemorrhage

Study design

TCD 3 times a week

CTA on day 5 and 10 (+/- 1 day)

Intervention

Comparison of CT angiography and Transcranial doppler in the detection of cerebral vasospasm after subarachnoid hemorrhage.

Contacts

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Eligibility criteria

Inclusion criteria

Aneurysmal subarachnoid hemorrhage

Age 18 years or older

Inclusion within 4 days after onset

Written informed consent

Exclusion criteria

Very poor prognosis

Renal insufficiency (eGFR < 60 ml/min/1.73m2)

Treatment with metformine

Inability to perform TCD (temporal bone window)

Contraindication for iodinated contrast agent (allergy, m. Kahler, myasthenia gravis, pheochromocytoma, mastocytosis, thyroid cancer, nuclear thyroid scan)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-09-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-09-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40069
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3985

Register	ID
NTR-old	NTR4157
CCMO	NL41458.042.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40069

Study results

Summary results

The results of this pilot study will be published in an international peer reviewed journal.