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

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

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

Samenvatting

ID

NL-OMON20699

Bron
Nationaal Trial Register

Verkorte titel
TACTICS

Aandoening

Subarachnoid hemorrhage. Cerebral vasospasm

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensitivity and specificity.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

TCD 3 times a week

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Aneurysmal subarachnoid hemorrhage

Age 18 years or older

Inclusion within 4 days after onset

Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-09-2013
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-09-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40069
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3985
NTR-old	NTR4157
CCMO	NL41458.042.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40069

Resultaten

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