Use of NIRS during mechanical thrombectomy for ischaemic stroke

Gepubliceerd: 10-10-2018 Laatst bijgewerkt: 18-08-2022

The NIRS monitor is capable of detecting changes in cerebral oxygenation

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

Samenvatting

ID

NL-OMON25450

Bron
Nationaal Trial Register

Verkorte titel
NIRS-IAT

Aandoening

Ischaemic stroke, Intra-arterial thrombectomy, Near infrared spectroscopy

Ischemische beroerte, intra-arteriële trombectomie, bijna infrarode spectroscopie

Ondersteuning

Primaire sponsor: University Medical Center Groningen, department of Anesthesiology
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Periprocedural cerebral oxygenation of the ischemic and non-ischemic hemisphere; specifically:

- Before and after the induction of anaesthesia
- Before and after the thrombectomy (reperfusion)
- Before and after the end of anaesthesia
2. Neurological outcome quantified by:
- NIHHS score

Toelichting onderzoek

Achtergrond van het onderzoek

Intra-arterial thrombectomy (IAT) is a well-proven method of restoring cerebral perfusion in patients suffering from an ischemic stroke. Anesthetic patient management during the IAT, on the other hand, is not evidence based. The existing guidelines are based on expert opinion and advise only broadly on periprocedural blood pressure management without accounting for any specific patient and procedural factors.

In brain tissue areas, where perfusion is critically low, functioning of the brain autoregulation mechanism is extremely challenged. Any further drops perfusion may lead to hypo-perfusion and irreversible ischemia while sudden increase in perfusion pressure, like after recanalization, can lead to hyper-perfusion and potentially to haemorrhagic conversion. Thus, there is a need for a measure of cerebral perfusion to guide and individualize the blood pressure management. Near infrared spectroscopy (NIRS) might provide the answer.

Doel van het onderzoek

The NIRS monitor is capable of detecting changes in cerebral oxygenation

Onderzoeksopzet

NIRS: continous collection of data througout the surgery

NIHHS: pre-procedure, after 24 hrs, at discharge
Modified Rankin scale: after 3 months

Onderzoeksproduct en/of interventie

Before the IAT, a NIRS sensor will be applied to the skull, bilaterally, directly above the flow region of the middle cerebral artery (MCA).

ADDENDUM (06-07-2019):
On arrival in the angiography suite, the NIRS sensors will be applied to the scalp bilaterally.

When eligible patients or their legal representatives are able to provide informed consent, NIRS sensors will be applied over the temporal lobes. If informed consent cannot be acquired before the start of the procedure, for example due to patient aphasia and/or absence of legal representatives, the NIRS sensors will be applied over the frontal lobes. Deferred consent will be sought and attained at a later date before the use of the data from these patients.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Equal or above 18 years of age

- An ischemic stroke caused by a proximal arterial occlusion of the MCA

- Eligible to undergo IAT under general anaesthesia

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Consent is not given by patient or his/her legal representative.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7323
NTR-old	NTR7539
Ander register	UMCG Research Register number : 201800631

Resultaten