Use of NIRS during mechanical thrombectomy for ischaemic stroke

No registrations found.

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

Summary

ID

NL-OMON25450

Source
Nationaal Trial Register

Brief title
NIRS-IAT

Health condition

Ischaemic stroke, Intra-arterial thrombectomy, Near infrared spectroscopy

Ischemische beroerte, intra-arteriële trombectomie, bijna infrarode spectroscopie

Sponsors and support

Primary sponsor: University Medical Center Groningen, department of Anesthesiology
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Demographic parameters

2. Radiological imaging:

- Location of the vascular occlusion and the level of collateral vasculature

- Modified Thrombolysis In Cerebral Infarction (mTICI)-score after thrombectomy

- Physiological and pharmacological variables before, during and after the procedure

- Physiological variables: Heart rate, invasive blood pressure, non-invasive blood pressure, FiO2, CO2, arterial haemoglobin saturation, EEG measure (if used)

- Pharmacological variables: drugs used, doses and concentrations administered

Study description

Background summary

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.

Study objective

The NIRS monitor is capable of detecting changes in cerebral oxygenation

Study design

NIRS: continous collection of data througout the surgery

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2018
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-10-2018
Application type:	First submission

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
NTR-new	NL7323
NTR-old	NTR7539
Other	UMCG Research Register number : 201800631

Study results