Serial arterial spin labeling perfusion MRI in acute ischemic stroke: detecting incomplete microvascular reperfusion.

Published: 10-09-2019
Last updated: 10-04-2024

To evaluate early cerebral perfusion changes of the ischemic brain after IVT and/or EVT in relation to progression of infarct core assessed by arterial Spin Labeling perfusion MRI.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vascular haemorrhagic disorders
Study type	Observational invasive

Summary

ID

NL-OMON47938

Source
ToetsingOnline

Brief title
Supermicro

Condition

- Vascular haemorrhagic disorders

Synonym
acute ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Contrast consortium

Intervention

Keyword: ischemic stroke, microvascular reperfusion, Perfusie MRI, Serial arterial spin labeling

Outcome measures

Primary outcome

The primary outcome of this study is the delta Cerebral Blood Flow (CBF) and

infarct volume between time points 0 and 60 minutes.

Secondary outcome

Secondary outcomes are the changes in CBF and concordant infarct volume

evolution over different time points early after treatment (+30, +90, +120,

+240 minutes).

Study description

Background summary

Intravenous tissue-type plasminogen activator (tPA) administration and endovascular treatment (EVT) in patients with acute ischemic stroke has led to recanalization rates up to 80% in recent clinical trials.
Although recanalization is essential for clinical recovery of stroke patients, about one third of patients do not recover to functional independence even despite fast and successful opening of the occluded vessel.

Recent findings suggest this discrepancy in treatment success and clinical outcome can to some extent be attributed to incomplete microvascular reperfusion (IMR).
Although IMR is suggested to be an important predictor of clinical outcome, little is known about microvascular reperfusion in acute stroke population and its relation to infarct evolution.

Study objective

To evaluate early cerebral perfusion changes of the ischemic brain after IVT and/or EVT in relation to progression of infarct core assessed by arterial Spin

Labeling perfusion MRI.

Study design

Single center prospective observational cohort study

Study burden and risks

Patients will undergo repeated MRI directly after intravenous tPA and/or EVT at multiple time points (+0, +30, +60, +90, +120, +240 minutes).
The current scan protocol does not require administration of any contrast media or ionizing radiation.

The patients will not directly benefit from participation in the study.
Scientific benefit: Data on changes in cerebral perfusion and infarct evolution seen on MRI directly after intravenous tPA and or EVT for ischemic stroke could potentially differentiate successful from unsuccessful recovery.

Results from this study add to the pathophysiological knowledge of acute ischemic stroke evolution, will provide novel imaging parameters useful as early outcome measures in stroke trials and could potentially contribute to the selection of patients eligible for additional (pharmacological) treatment.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-A clinical diagnosis of acute ischemic stroke
-Age 18 years or older
-NIHSS >/=2
-Treated with intravenous tPA <4.5 h after symptom onset and/or treated with EVT <6 hours after
symptom onset for a large vessel occlusion of the anterior circulation
(distal intracranial carotid artery or middle cerebral artery (M1 segment or proximal M2 segment))
confirmed by neuroimaging (CTA or MRA) resulting in a successful recanalization (defined as
mTICI 2B-3)
-Written informed consent obtained

Exclusion criteria

-Any previous stroke or known neurological disorder associated with structural brain abnormalities
-Any contra-indication for MRI (e.g. ferromagnetic implant(s), claustrophobia, pacemaker)
-Clinical condition unsuited for repetitive MRI imaging or prolonged stay at the Radiology department.
-Pre-stroke modified Rankin Scale score > 2
-Participation in stroke trials interfering with the current study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-09-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL69823.078.19