Reperfusion of the brain after endovascular thrombectomy for ischemic stroke: development of novel prognostic imaging biomarkers using magnetic resonance imaging

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The objective of this study is to assess the prognostic value of early perfusion changes and infarct evolution detected with magnetic resonance imaging (MRI) acquired directly after EVT.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON52283

Source
ToetsingOnline

Brief title
Reperfuse

Condition

- Central nervous system vascular disorders
- Embolism and thrombosis

Synonym
cerebral infarction, 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

Intervention

Keyword: MRI, reperfuse, stroke, thrombectomy

Outcome measures

Primary outcome

The primary outcome of this study is the National Institutes of Health Stroke

Scale (NIHSS) 24 hours after successful recanalization.

Secondary outcome

Secondary radiological outcomes at 24 hours after successful recanalization:

- infarct volume on DWI/FLAIR

- intracerebral haemorrhage according to the Heidelberg Bleeding

Classification10 on SWI

- recanalization status on MRA

Secondary clinical outcomes:

- Modified Rankin Scale (mRS) score at 90 days (± 14 days)

- symptomatic intracranial haemorrhage (defined as haemorrhage detected on

brain imaging with >=4 points increase in NIHSS)

Study description

Background summary

Endovascular thrombectomy (EVT) is a highly effective treatment for acute

ischemic stroke, leading to recanalization rates of up to 80%. However, still approximately one-third of patients do not recover to functional independence, despite fast and complete reopening of the occluded artery by EVT. Clinical evidence suggests that tissue reperfusion (i.e., complete restoration of the downstream blood flow) is a better predictor of outcome than recanalization (i.e., opening of the occluded artery). However, post-procedural surrogate markers useful for discriminating successful from unsuccessful reperfusion are lacking. Such markers are highly needed for selecting patients who may benefit from additional (pharmacological) treatment.

Study objective

The objective of this study is to assess the prognostic value of early perfusion changes and infarct evolution detected with magnetic resonance imaging (MRI) acquired directly after EVT.

Study design

This is a single center prospective, observational cohort study conducted within the Erasmus MC University Medical Center. It is a within-subject ischemic stroke evaluation carried out with MRI. The expected study duration is 18 months.

Study burden and risks

Participants will undergo an MRI scan with administration of contrast material directly after successful EVT and a second MRI scan without administration of contrast material 24 hours after treatment. The current scan protocol does not require exposing patients to any ionizing radiation. Additionally, functional status (mRS score) will be assessed by telephone interview at 90 days after treatment. Participants will not directly benefit from participation in this study. Data on changes in cerebral perfusion and infarct evolution seen on MRI directly after treatment could potentially differentiate successful from unsuccessful recovery. Results from this study may thereby provide novel imaging biomarkers useful as early outcome measures and contribute to the selection of patients eligible for additional (pharmacological) treatment.

Contacts

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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
- Treated with EVT for a large vessel occlusion of the anterior circulation (intracranial carotid artery or middle cerebral artery (M1 segment or M2 segment) confirmed by neuroimaging (CTA or MRA) resulting in a successful recanalization (defined as eTICI >= 2B)
- Written informed consent obtained

Exclusion criteria

- Pre-stroke disability which interferes with assessment of functional outcome at 90 days, i.e. mRS >2
- Contraindication(s) for MRI (e.g. claustrophobia, pacemaker, metallic implant, known contrast allergy)
- Clinical condition unsuited for MRI imaging or prolonged stay at the Radiology department (e.g. agitation and restlessness, neurologic deterioration)
- Use of general anesthesia during EVT

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-02-2022
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	NL79093.078.21