Long-term follow-up MR CLEAN-NO IV: evaluation of long-term outcomes after acute ischemic stroke.

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The aim of this study is to assess the long-term outcomes (up to 36 months) and costs of stroke after EVT treatment, including direct EVT and IVT followed by EVT.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53154

Source
ToetsingOnline

Brief title
Long-term follow-up MR CLEAN-NO IV

Condition

- Other condition
- Central nervous system vascular disorders
- Embolism and thrombosis

Synonym
brain infarction, Stroke

Health condition

Beroerte

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: TKI-PPP Health Holland

Intervention

Keyword: Costs, Long-term follow-up, MRI, Stroke

Outcome measures

Primary outcome

The primary outcomes are (1) the score on the modified Rankin Scale (mRS), as functional outcome measure from 0 (no symptom) to 6 (death), at 18, 24, 30 or 36 months after AIS and (2) long-term evolution of stroke lesions through acquisition of a 24-month (range 18 to 36 months) follow-up MRI scan.

Secondary outcome

The secondary outcomes include the quality of life, Barthel index, major vascular events, and costs related to stroke, both medical costs and productivity loss, at 18, 24, 30 or 36 months. In addition we aim to include deep leaming reconstruction, in which common image describïng parameters such peak signal to noise ratio (pSNR), structural similarity (SSIM) and sharpness will be evaluated.

Study description

Background summary

Endovascular thrombectomy (EVT) improves early clinical outcomes in acute ischemic stroke (AIS) patients. The MR CLEAN-NO IV trial has been conducted to assess the effects of direct EVT compared with IVT followed by EVT in patients with AIS caused by computed tomography angiography confirmed anterior circulation occlusion in the Netherlands. However, long-term outcomes and costs

after direct EVT are lacking.

Study objective

The aim of this study is to assess the long-term outcomes (up to 36 months) and costs of stroke after EVT treatment, including direct EVT and IVT followed by EVT.

Study design

The multicenter prospective study will be performed to collect the long-term outcomes of patients who participated in the MR CLEAN-NO IV trial between January 2018 and October 2020. The first part of the study involves contacting patients once by telephone to collect clinical outcomes at 18, 24, 30 or 36 months after stroke, depending on the moment of study enrollment in the MR CLEAN-NO IV trial. At the same time, these patients will be invited to fill out two questionnaires on medical consumption and productivity loss either via post or email to collect cost data. The second part of the study will involve long-term evolution of stroke lesions through acquisition of a 24-month (range 18 to 36 months) follow-up MRI scan.

Intervention

The intervention group will undergo immediate IAT using a stent retriever, as recommended by the steering committee. The standard care group will receive IVT 0.9 mg/kg with a maximum dose of 90 mg in one hour, followed by IAT using a stent retriever.

Study burden and risks

It is foreseen that no risks are associated with participation, as there are no risks associated with questionnaires or assessment of MRI at 3T when regular contraindications for MRI are followed.

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

All subjects enrolled in the MR CLEAN-NO IV trial.
For patients that are also invited for the follow-up MRI scan, the following additional criteria apply:
- 24-hours follow-up MRI scan available.
- Patiënt is able to come to the Amsterdam UMC by themselves or supported by family or friends.

Exclusion criteria

Only for patients that are invited to the follow-up MRI scan the following exclusion criteria apply:
- Default research screening associated with a MRI scan (see attachment 'vragen testpersonen 3TMRI_NL')
- Patiënt who are mobility impaired, as the study requires them to travel to the hospital.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2018
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-03-2022
Application type:	Amendment
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
ISRCTN	ISRCTN80619088
CCMO	NL58320.078.17

Study results

Date completed: 05-02-2021

Actual enrolment: 487

Summary results
Trial is onging in other countries