MR CLEAN: a multicenter randomized clinical trial of endovascular treatment for acute ischemic stroke in The Netherlands.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27679

Source
NTR

Brief title
MR CLEAN

Health condition

Acute ischemic stroke, intracranial arterial occlusion, thrombolysis, mechanical thrombectomy

Sponsors and support

Primary sponsor: This is an investigator driven trial.
co principal investigators are:
Yvo Roos MD AMC Amsterdam
Charles Majoie AMC Amsterdam
Aad van der Lugt Erasmus MC Rotterdam
Robert van Oostenbrugge, AZM Maastricht
Paul Hofman, AZM Maastricht.
Source(s) of monetary or material Support: Netherlands Heart Foundation (2008T030)
Additional funding from the industry through unrestricted grants is being sought.

Intervention

Outcome measures

Primary outcome

The score on the modified Rankin scale at 90 days.

Secondary outcome

Imaging parameters:

1. Vessel recanalization at 24-48 hours after treatment, assessed by CTA or MRA;

2. Infarct size at 24-48 hours assessed by CT;

3. (A-)symptomatic intracerebral hemorrhage at 24-48 hours assessed by CT.

Clinical parameters:

1. Mortality at 1 week and at 90 days;

2. The score on the NIH stroke scale at 24-48 hours after treatment;

3. The score on the NIH stroke scale at 1 week or at discharge.

Functional outcome:

1. Score on the EQ5D at 90 days;

2. Barthel index at 90 days;

3. Score on the Academic Linear Disability Scale at 90 days.

Study description

Background summary

Endovascular treatment increases the likelihood of recanalization in patients with acute

ischemic stroke caused by proximal intracranial arterial occlusion. The purpose of the Multicenter Randomized Clinical trial of Endovascular treatment for Acute ischemic stroke in the Netherlands (MR CLEAN) is to assess the safety and effect on functional outcome of endovascular treatment in such patients.
DESIGN:

MR CLEAN is a pragmatic phase III multicenter randomized clinical trial with blind outcome assessment. We compare endovascular treatment (intra-arterial thrombolysis, mechanical thrombectomy or both) with no treatment, against a background of optimal medical management, which may include intravenous alteplase.
Patients should have a clinical diagnosis of acute ischemic stroke, confirmed by MRI or CT, an NIHSS score of 2 points or more, a relevant intracranial arterial occlusion, demonstrated by CTA, MRA or TCD and the possibility to start endovascular treatment within 6 hours after stroke onset.
The exact choice of endovascular treatment modality for each patient is left to the discretion of the local investigator and treating physicians. The steering committee will release recommendations and guidelines for treatment and selection of patients in the study.

STUDY OUTCOMES:

The primary outcome is the score on the modified Rankin scale 3 months after inclusion in the study. Secundary outcomes are the NIHSS score at 48 hours, vessel patency, score on the Barthel index, and the occurrence of major bleeding.
Randomization will be stratified for treatment with iv rtPA, stroke severity according to the National Institutes of Health Stroke Scale, intended mechanical thrombectomy and center. We will estimate the effect of treatment by means of the sliding dichotomy approach, which considers the whole range of the mRS. In total, 500 patients will be included.

DISCUSSION:

MR CLEAN is a pragmatic trial. Centers from other countries than the Netherlands are welcome to join the study. Inclusion of patients will take 4 years, and starts early in 2010.

Study objective

The null hypothesis for this study is that endovascular treatment for acute ischemic stroke with onset of less than six hours in patients with a symptomatic intracranial proximal arterial occlusion, leads to a similar distribution of functional outcomes as standard treatment.

Study design

First patient in: april 2010.

Last patient out: July 2014.

Intervention

Intra-arterial treatment (rtPA and/or mechanical thrombectomy) versus no intra-arterial treatment. The treatment is provided in addition to best medical management, including intravenous thrombolysis.

Contacts

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Eligibility criteria

Inclusion criteria

1. A clinical diagnosis of acute stroke, with a deficit on the NIH stroke scale of > 2 points;

2. CT or MRI scan rules out intracranial hemorrhage;

3. Intracranial arterial occlusion of the distal intracranial carotid artery or middle (M1/M2) or anterior (A1/A2) cerebral artery, demonstrated with CTA, MRA, DSA or transcranial Doppler/duplex (TCD);

4. The possibility to start treatment within 6 hours from onset;

5. Informed consent given;

6. Age 18 or over.

Exclusion criteria

1. Cerebral infarction within the previous 6 weeks;

2. History of intracerebal hemorrhage;

3. Severe head injury the previous 4 weeks;

4. Major surgery, gastrointestinal bleeding or urinary tract bleeding within 2 weeks;

5. Arterial blood pressure > 185/110 mmHg;

6. Blood glucose < 2.7 or > 22.2 mmol/l;

7. Platelet count <90 x 10*9/L;

8. APTT>50 s or INR >1.7;

9. Intravenous treatment with thrombolytic therapy in a dose exceeding 0.9 mg/kg rtPA or 90 mg.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	500

Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL695
NTR-old	NTR1804
Other	NHS (Netherlands Heart Foundation) : 2008T030
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A