Multi Center Clinical trial of endovascular treatment of acute ischemic stroke in the Netherlands.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON39683

Source
ToetsingOnline

Brief title
MR CLEAN

Condition

- Central nervous system vascular disorders
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
brain infarct, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: AngioCareBV,Concentrics,ev3 International,Medac,Nederlandse hartstichting,PENUMBRA

Intervention

Keyword: -clinical trial, -endovascular treatment, -ischemic stroke, -thrombolysis

Outcome measures

Primary outcome

The primary outcome is the score on the modified Rankin scale 90 days after inclusion in the study.

Secondary outcome

Imaging:

-Vessel recanalization at 24 hours after treatment, assessed by CTA or MRA. The criteria for recanalization on CTA or MRA are based on a modified AOL score and the clot burden score

-Infarct size at 24 hours assessed by CT, using standard methods, including manual tracing of the infarct perimeter and semiautomated pixel thresholding.

-CTA or MRA at 72 hours will be compared with baseline vessel imaging data, to estimate the recanalization rate. Perfusion CT at baseline is optional, but available at most centers. Infarct size at 24 hours will be compared with plain CT and perfusion CT results at baseline.

Clinical parameters

-NIHSS , including NIH supplemental motor score, at 24 hours.

-NIHSS at 1 week or at discharge.

Functional outcome at three months

-Barthel

-EQ5D

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 these patients.

Study objective

The primary objective of this study is to estimate the effect of endovascular treatment on overall functional outcome after acute ischemic stroke of less than six hour duration, in patients with a symptomatic anterior circulation IAO. The secondary objectives are to assess the overall safety of endovascular treatment with regard to the occurrence of hemorrhagic and ischemic complications, the efficacy with regard to obtaining recanalization, and to evaluate predictors of recanalization, including imaging aspects and hemostatic parameters. Moreover, we want to assess the safety and efficacy of different types of endovascular treatment (i.e. mechanical treatment, intra-arterial thrombolysis) different combinations of treatment (i.e. with intravenous rtPA) and different timings of treatment. Tertiary objectives are to carry out case studies of implementation strategies and loco-regional solutions for barriers to the delivery of endovascular treatment for acute ischemic stroke and to collect data for cost-effectiveness analysis of endovascular treatment compared with standard treatment.

Study design

MR CLEAN is a pragmatic phase III multicenter randomized clinical trial with blinded outcome assessment. We compare endovascular treatment (intra-arterial thrombolysis, mechanical treatment or both) with no treatment, against a

background of optimal medical management, which may include intravenous alteplase.
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 provide recommendations and guidelines for treatment and selection of patients in the study.

Intervention

The intervention contrast is endovascular treatment versus no endovascular treatment. The treatment is provided in addition to best medical management (aspirin, stroke unit treatment and intravenous thrombolysis if indicated).

Intra-arterial treatmetn consists of intra-arterial thrombolysis with alteplase or urokinase, and/or mechanical treatment (stenting, aspiration or retraction of the thrombus). Specific recommendations with regards to procedures and devices will be issued by the trial steering committee and are listed in appendix 3.

Study burden and risks

All patients that participate in the trial will undergo a second CTA within 24 hours after admission and an CT scan at day 5-7. All patients will have a telephone interview at three months. Future patients will be included in the economic evaluation of the MR CLEAN. In addition to an economic questionnaire they will undergo a telephonic interview with an interval of 6 months.

In case patients are randomized for intra-arterial treatment they sometimes need sedation or anesthesia and intubation during the procedure. Endovascular treatment is associated with increased risk of intra-cerebral hemorrhage.

Adverse events are listed in paragraph 7.1 (page 18) of the protocol.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
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 stroke, with a deficit on the NIH stroke scale of more than 2 points.
• CT or MRI scan ruling out intracranial hemorrhage.
• Intracranial arterial occlusion of the distal intracranial carotid artery or middle (M1/M2) or anterior (A1/A2) cerebral artery, demonstrated with CTA, MRA or DSA.
• The possibility to start treatment within 6 hours from onset.
• Informed consent given.
• Age 18 or over.

Exclusion criteria

- cerebral infarction in past 6 weeks
-history in intracerebral bleeding
-RR > 185/110 unresponsive to antihypertensive agents
-blood glucose of < 2.7 or > 22.2
-Clinical signs of hemorrhagic diathesis or platelet count <90 x 10*9/L, APTT>50 sec or INR >1.7
- intravenous treatment with thrombolysis with a dose exceeding 0.9mg/kg or 90 mg
-patients who are treated with intravenous thrombolysis while having cantra-indications for it.;Exclusion criteria for mechanical thrombectomy
- carotid artery stenosis over 70% (NASCETT) which cannot be stented
-RR > 185/110
-Blood glucose < 2.7 or >22.2

-INR > 3.0 or platelet count < 40 x 10*9

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	500
Type:	Actual

Medical products/devices used

Generic name:	Mechanical device developed for vessel recanalization
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Actilyse
Generic name:	alteplase (rtPA)
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	medacinase
Generic name:	urokinase
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-02-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-05-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-06-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	

Date:	09-04-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-10-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-08-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2014
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
EudraCT	EUCTR2009-017315-15-NL
ISRCTN	ISRCTN10888758
CCMO	NL30557.078.10