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

Gepubliceerd: 07-05-2009 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27679

Bron
NTR

Verkorte titel
MR CLEAN

Aandoening

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

Ondersteuning

Primaire sponsor: This is an investigator driven trial.
co principal investigators are:
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Robert van Oostenbrugge, AZM Maastricht
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Overige ondersteuning: Netherlands Heart Foundation (2008T030)
Additional funding from the industry through unrestricted grants is being sought.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The score on the modified Rankin scale at 90 days.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

First patient in: april 2010.

Last patient out: July 2014.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL695
NTR-old	NTR1804
Ander register	NHS (Netherlands Heart Foundation) : 2008T030
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A