Cost-effectiveness analyses and LOng Term follow-up in patients randomised in a Multicenter Randomized CLinical trial of Endovascular treatment for Acute ischemic stroke in The Netherlands

Gepubliceerd: 26-02-2015 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24159

Bron
NTR

Verkorte titel
CLOT-MR CLEAN

Aandoening

endovasculartreatment, acute ischemic stroke, randomized controlled trial, cost-effectiveness, long-term follow-up

endovasculaire behandeling, acuut herseninfarct, gecontroleerd gerandomiseerd onderzoek, kosteneffectiviteit, lange termijn uitkomsten

Ondersteuning

Primaire sponsor: Academical Center Amsterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. modified Rankin scale and quality of life at 2 years after randomization
2. costs per patient without poor outcome on the Modified Rankin Scale (mRs) and the costs per quality-adjusted life year (QALY) at 2 years after randomization

Toelichting onderzoek

Achtergrond van het onderzoek

The current study describes a cost-effectiveness analysis on top of a large clinical trial investigating the effect of
endovascular treatment on overall functional outcome after acute ischemic stroke. This so-called MR CLEAN trial is funded by the Netherlands Heart Foundation and is including patients since 2010. It will generate data on
efficacy, safety and effectiveness of cerebral endovascular treatment, and will provide important information on logistics and implementation of endovascular treatment in the Netherlands. However, it is also mandatory to study the cost effectiveness of this new and expensive treatment modality and assess its health care budget impact before large scale implementation eventually starts. The MR CLEAN trial is an ideal setting for measuring the societal costs related to endovascular treatment after strok. The current study will measure all direct and indirect medical as well as direct non-medical costs of treating stroke patients in the trial, thereby enabling a full economic evaluation of cerebral endovascular treatment (against standard care) from a societal perspective with the costs per patient with poor outcome and the costs per quality-adjusted life year as the outcome parameters. The time horizon will be two years. Long-term consequences of endovascular treatment in patients with cerebral infarction beyond two years until the end of life will be addressed in a model-based analysis assuming different scenarios of natural courses of stroke. In addition, a budget impact analysis is proposed by combining the health care cost data with national incidence and prevalence estimates of stroke. The MR CLEAN trial itself will answer the question whether higher recanalization rates improve functional outcome and quality of life. The current proposal will investigate whether the treatment can be considered to be cost-effective and what the Dutch Health Care budget impact will be.

Onderzoeksopzet

3 months, 6 months, 1 year, 1,5 years and 2 years

Onderzoeksproduct en/of interventie

endovascular treatment consist of arterial catheterization with a microcatheter to the level of occlusion and delivery of a thrombolytic agent and/ or mechanical thrombectomy.
Both alteplase and urokinase for intra-arterial thrombolysis is allowed into the trial, a dose of 1 mg alteplase is considered to be equivalent to 10.000-15.000 U urokinase.44
Mechanical treatment may consist of mechanical thrombectomy, aspiration, or stenting.
Specific recommendations with regards to procedures and devices will be issued regularly by the trial steering committee.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Neurology, H2
P.O. Box 22660.
Y.B.W.E.M. Roos
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663842

Wetenschappelijk

Academic Medical Center (AMC), Department of Neurology, H2
P.O. Box 22660.
Y.B.W.E.M. Roos
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663842

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

INCLUSION CRITERIA

• A clinical diagnosis of acute stroke, with a deficit on the NIH stroke scale of 2 points or more.

• 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, DSA or transcranial Doppler/duplex (TCD).

• The possibility to start treatment within 6 hours from onset.

• Informed consent given.

• Age 18 or over.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

GENERAL EXCLUSION CRITERIA

• Arterial blood pressure > 185/110 mmHg.

• Blood glucose < 2.7 or > 22.2 mmol/L.

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

• Intravenous treatment with thrombolytic therapy despite contra-indications, i.e. major surgery, gastrointestinal bleeding or urinary tract bleeding within the previous 2 weeks, or arterial puncture at a non-compressible site within the previous 7 days.

SPECIFIC EXCLUSION CRITERIA FOR INTENDED MECHANICAL THROMBECTOMY

• Laboratory evidence of coagulation abnormalities, i.e. platelet count <40 x 109/L, APTT>50 sec or INR >3.0.

SPECIFIC EXCLUSION CRITERIA FOR INTENDED INTRA-ARTERIAL THROMBOLYSIS

• Cerebral infarction in the distribution of the relevant occluded artery in the previous 6 weeks.

• History of intracerebral hemorrhage.

• Severe head injury (contusion) in the previous 4 weeks.

• Clinical or laboratory evidence of coagulation abnormalities, i.e. platelet count <90 x 109/L, APTT>50
sec or INR >1.7. Current treatment with oral thrombin antagonists, such as argatroban and dabigatran or treatment with oral selective Factor Xa inhibitors, such as rivaroxaban.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2010
Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-02-2015
Soort:	Eerste indiening

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	NL4733
NTR-old	NTR5073
Ander register	: Dossiernumber ZonMW 837004005

Resultaten

Samenvatting resultaten
none