Dual thrombolytic therapy with mutant pro-urokinase and low dose alteplase for ischemic stroke

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29554

Source
Nationaal Trial Register

Brief title
DUMAS

Health condition

Stroke, Ischemic stroke, Thrombolytic therapy, Treatment

Sponsors and support

Primary sponsor: Erasmus Medical Center, ROtterdam
Source(s) of monetary or material Support: DUMAS is sponsored by an unrestricted grant from Thrombolytic Science International (TSI), paid to the institution

Intervention

Outcome measures

Primary outcome

The primary outcome is any post-intervention intracranial haemorrhage on MRI according to the Heidelberg Bleeding Classification within 24-48 hours of study drug administration.

Secondary outcome

- Score on the NIHSS assessed at 24 hours and 5-7 days post-treatment.

- Improvement of at least 4 points on NIHSS at 24 hours compared to baseline, or (near) complete recovery (NIHSS 0 or 1)

- Score on the mRS assessed at 90 days

- Infarct volume with MRI at 24 hours

- Secondary blood biomarkers of thrombolysis (including fibrinogen and d-dimer)

Study description

Background summary

Randomized controlled phase II trial to test the safety and preliminary efficacy of a dual thrombolytic treatment consisting of a small intravenous (IV) bolus of alteplase followed by IV infusion of mutant pro-urokianse against usual treatment with IV alteplase in patients presenting with ischemic stroke.

Study objective

To test the safety and preliminary efficacy of a dual acute thrombolytic treatment consisting of a small intravenous (IV) bolus of alteplase followed by IV infusion of HisproUK against usual treatment with IV alteplase in patients presenting with ischemic stroke

Study design

30 day follow-up

Intervention

Bolus of IV alteplase (5 mg) followed by continuous infusion of HisproUK 40 mg/hr during 60 minutes. Depending on results of interim analyses, the alternate dose may be revised to a lower dose (30mg/hr during 60 minutes) or a higher dose (50mg/hr during 60 minutes).

Contacts

Public

Erasmus MC University Medical Center, Department of Neurology, suite Ee 2240a, 3015 CE Rotterdam, The Netherlands
DUMAS trial office
Rotterdam 3000 CA
The Netherlands
0639583967
Scientific
Erasmus MC University Medical Center, Department of Neurology, suite Ee 2240a, 3015 CE Rotterdam, The Netherlands
DUMAS trial office
Rotterdam 3000 CA
The Netherlands
0639583967

Eligibility criteria

Inclusion criteria

- A clinical diagnosis of ischemic stroke;

- A score of at least 1 on the NIH Stroke Scale;

- CT ruling out intracranial hemorrhage;

- Treatment possible within 4.5 hours from symptom onset or last seen well;

- Meet the criteria for standard treatment for IV alteplase according to national guidelines;

- Age of 18 years or older;

- Written informed consent (deferred).

Exclusion criteria

- Candidate for endovascular thrombectomy (i.e., a proximal intracranial large artery occlusion on CTA);

- Contra-indication for standard treatment with IV alteplase according to national guidelines;

- Pre-stroke disability which interferes with the assessment of functional outcome at 90 days, i.e. mRS > 2;

- Known pregnancy;

- Participation in any medical or surgical intervention trial other than current.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-08-2019
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-11-2018
Application type:	First submission

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	NL7409
NTR-old	NTR7634
Other	METC Erasmus MC : 2018-00448-42 EudraCT

Study results

Summary results
None