

No registrations found.

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

Summary

Source

NTR

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-urokinase 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

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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
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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