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

Gepubliceerd: 26-11-2018 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON29554

Bron
Nationaal Trial Register

Verkorte titel
DUMAS

Aandoening

Stroke, Ischemic stroke, Thrombolytic therapy, Treatment

Ondersteuning

Primaire sponsor: Erasmus Medical Center, ROtterdam
Overige ondersteuning: DUMAS is sponsored by an unrestricted grant from Thrombolytic Science International (TSI), paid to the institution

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

30 day follow-up

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-08-2019
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-11-2018
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	NL7409
NTR-old	NTR7634
Ander register	METC Erasmus MC : 2018-00448-42 EudraCT

Resultaten

Samenvatting resultaten
None