

Thrombolysis and Uncontrolled Hypertension

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We hypothesize that the active strategy leads to a better functional outcome than the conservative strategy three months after acute ischemic stroke, in patients with elevated pre-treatment blood pressure otherwise eligible for intravenous...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22259

Bron

NTR

Verkorte titel

TRUTH

Aandoening

Ischemic stroke, blood pressure, intravenous thrombolysis, herseninfarct, bloeddruk, intraveneuze trombolysie.

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam

Overige ondersteuning: NutsOhra Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Functional outcome (modified Rankin Scale) at three months.

Toelichting onderzoek

Achtergrond van het onderzoek

Intravenous thrombolysis (IVT) with recombinant tissue plasminogen activator is an effective treatment in acute ischemic stroke. However, IVT is contraindicated when blood pressure (BP) is above 185/110 mm Hg, because of an increased risk on symptomatic intracranial hemorrhage (sICH). In Dutch clinical practice, two distinct strategies are used in this situation.

The active strategy comprises lowering BP with antihypertensive agents below these thresholds to allow start of IVT. In the conservative strategy, IVT is administered only when BP drops spontaneously below protocolled thresholds.

We hypothesize that the active strategy leads to a better functional outcome three months after acute ischemic stroke. Secondary hypotheses are that this effect occurs despite increasing the number of sICHs, and could be attributable to a higher rate of IVT treatments and a shorter door-to-needle time.

The TRUTH is a prospective, observational, cluster-based, parallel group follow-up study; in which participating centers continue their current local treatment guidelines. Outcomes of patients admitted to centers with an active will be compared to those admitted to centers with a conservative strategy.

The TRUTH is the first large prospective study specifically studying IVT-candidates with elevated BP, and has the potential to change clinical practice and optimize acute stroke care in these patients.

Doel van het onderzoek

We hypothesize that the active strategy leads to a better functional outcome than the conservative strategy three months after acute ischemic stroke, in patients with elevated pre-treatment blood pressure otherwise eligible for intravenous thrombolysis.

Secondary hypotheses are that this effect occurs despite increasing the number of sICHs, and could be attributable to a higher rate of IVT treatments and a shorter door-to-needle time.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients admitted to centers with an active strategy will be compared to those admitted to centers with a conservative strategy.

Contactpersonen

Publiek

[default]

The Netherlands

Wetenschappelijk

[default]

The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18 years or above.
- Intravenous thrombolysis indicated.
- Intravenous thrombolysis postponed or withheld because of blood pressure above 185/110 mmHg.
- No contraindications for IVT other than high blood pressure.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	1235
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	28-07-2015
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

NTR-new

NTR-old

Ander register

ID

NL5184

NTR5332

: W14_243 # 14.17.0295

Resultaten