

Thrombolysis and Uncontrolled Hypertension

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22259

Source

NTR

Brief title

TRUTH

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam

Source(s) of monetary or material Support: NutsOhra Foundation

Intervention

Outcome measures

Primary outcome

Functional outcome (modified Rankin Scale) at three months.

Secondary outcome

Symptomatic intracranial hemorrhage

Door-to-needle time

Intravenous thrombolysis rate

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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

Contacts

Public

[default]
The Netherlands

Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015
Enrollment:	1235
Type:	Anticipated

Ethics review

Positive opinion	
Date:	28-07-2015
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	NL5184
NTR-old	NTR5332
Other	: W14_243 # 14.17.0295

Study results