Antiplatelet therapy in combination with Recombinant t-PA Thrombolysis in Ischemic Stroke.

No registrations found.

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

Summary

ID

NL-OMON24653

Source
NTR

Brief title
ARTIS

Health condition

Re-occlussion in ischemic stroke.

Sponsors and support

Primary sponsor: Netherlands Heart Foundation (Nederlandse Hartstichting).

Intervention

Outcome measures

Primary outcome

The primary objective of the ARTIS-Trial is to investigate whether the addition of acute APT to standard rt-PA thrombolysis reduces poor outcome 3 months after an acute ischemic stroke. Poor outcome is defined as death or dependency (mRS 3-6).

Secondary outcome

The secondary objectives are to investigate complications within 48 hours after randomisation like:

- the occurrence of symptomatic intracranial haemorrhage and serious systemic bleeding;

- neurological symptoms 7 – 10 days after randomisation or at discharge if the patient is discharged within 7 days;

- survival at 3 months;

- disability at 3 months;

- functional health at 3 months non-dichotomized (ordinal mRS);

- causes of poor outcome.

Study description

Background summary

One of the major problems observed in rt-PA thrombolysis in ischemic stroke is the phenomenon of clinical deterioration following initial improvement probably due to reocclusion of the vessel. Acute treatment of ischemic stroke only addresses the degradation of fibrin while a thrombus is formed by both finbrin formation and platelet activation. Reocclusion can be prevented by adding antiplatelet therapy (APT) to rt-PA thrombolysis as has been proven effective in several thrombloysis studies in myocardial infarction.

The ARTIS-Trial is a phase III multicenter trial with an Prospective, Randomized, Open treatment, Blind Endpoint (PROBE) design that will enroll 800 patients (400 in each arm). Purpose of the trial is to determine whether adding acute APT to rt-PA thrombolysis in ischemic stroke improves functional outcome at 3 months.
Patients with an ischemic stroke eligble for rt-PA thrombolysis are randomised to receive 300mg acetylsalicylic acid intravenously (Asp¨¦gic) within 1.5 hours after the rt-PA bolus or standard care. Primary outcome will be poor functional outcome at 3 months, defined as dependency or death (modified Rankin score 3-6). Among secondary end points are symptomatic intracranial or serious systemic haemorrhages within 48 hours

Study objective

We hypothesis that antiplatelet therapy adjunctive to rt-PA thrombolysis improves outcome by preventing re-occlusion in terms of three months clinical outcome.

Study design

N/A

Intervention

Patients are randomized to receive either 300 mg acetylsalicylic acid iv (Aspégic) within 1,5 hours after the rt-PA bolus or standard care of rt-PA without Aspégic.

Contacts

Public
Academic Medical Center
Department of Neurology
Postbus 22660

S.M. Zinkstok
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111
Scientific
Academic Medical Center
Department of Neurology
Postbus 22660

S.M. Zinkstok
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

1. Patients with an acute ischemic stroke receiving rt-PA thrombolysis

2. Age ≥ 18 years

3. Written informed consent is obtained

Exclusion criteria

1. Known APT in the previous 5 days(in case of uncertainty the patient may be included)

2. Known thrombocytopenia (thrombocyte count ≥ 100 * 10E9/l)

3. Known contra-indications to ASA treatment (e.g. previous adverse reaction to ASA)

4. Known anticoagulance usage in the previous 5 days

5. Known legal incompetence of the patient prior to this stroke

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-07-2008
Enrollment:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-11-2006
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	NL809
NTR-old	NTR822
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Early administration of aspirin in patients treated with alteplase for acute ischaemic stroke: a randomised controlled trial.
Sanne M Zinkstok, Yvo B Roos, on behalf of the ARTIS investigators.
www.thelancet.com Published online June 28, 2012
http://dx.doi.org/10.1016/S0140-6736(12)60949-0.