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

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The objective of this trial is to investigate whether adding acute APT to rt-PA thrombolysis in ischemic stroke reduces death or dependency at 3 months.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON31665

Source
ToetsingOnline

Brief title
ARTIS-Trial

Condition

- Central nervous system vascular disorders
- Embolism and thrombosis

Synonym
ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nederlandse hartstichting

Intervention

Keyword: antiplatelet, ischemic stroke, rt-PA, thrombolysis

Outcome measures

Primary outcome

The primary endpoint is poor functional health at 3 months defined as

dependency or death (mRS 3 * 6).

Secondary outcome

Secondary outcomes are symptomatic intracranial or serious systemic

haemorrhages within 48 hours, neurological symptoms at 7 * 10 days and

survival, disability assessed with the ALDS scale, functional health on the

full ordinal range of the modified Rankin Scale at 3 months and the causes of

poor outcome.

Study description

Background summary

Stroke is a major cause of acquired disability in the Netherlands. In recent years the acute treatment of ischemic stroke improved significantly. Treatment with rt-PA within 3 hours reduced the relative risk of poor outcome by 20%, leading to a favourable outcome of 40%. Treatment with rt-PA however only addresses the degradation of fibrin while a thrombus is formed by both fibrin formation and platelet activation. Currently no treatment is given in the acute phase of ischemic stroke to inhibit the platelet activation, while in acute myocardial infarction outcome improved by adding acute antiplatelet therapy to thrombolysis.

Subgroup-analysis of patients in the NINDS trial already on anti-platelet therapy (APT) revealed that they had a better outcome compared to thrombolysed patients without APT. Patients already on APT had less clinical deteriorations (often caused by re-occlusion), without increase in the risk of intracranial haemorrhages. We therefore hypothesize that the addition of APT to rt-PA improves the efficiency and speed of thrombolysis itself and prevents

re-occlusion.

Study objective

The objective of this trial is to investigate whether adding acute APT to rt-PA thrombolysis in ischemic stroke reduces death or dependency at 3 months.

Study design

Multi-center clinical trial with web-based Oracle Clinical data entry using a PROBE design: Prospective, Randomized, Open label design with Blind Endpoint assessment.

Intervention

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

Study burden and risks

Patients risk hemorrhages. Trials have shown that patients using classic antiplatelet therapy, like the ASA used in the this trial, prior to the stroke did not suffer more hemorrhage and bleeding. The risk of these complications are therefore estimated to be limited while the benefits are estimated to be high in term of less death and dependency after three months.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* patients with an acute ischemic stroke receiving rt-PA thrombolysis
* age * 18 years
* written informed consent is obtained

Exclusion criteria

* known APT in the previous 5 days(in case of uncertainty the patient may be included)
* known thrombocytopenia (thrombocyte count * 100 * 10E9/l)
* known contra-indications to ASA treatment (e.g. previous adverse reaction to ASA)
* Known anticoagulans usage in the previous 5 days
* known legal incompetence of the patient prior to this stroke

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	800
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	acetylsalicyclic acid
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	21-01-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2006-006829-13-NL
Other	Nederlandse trialreg. 822

Register	ID
CCMO	NL15747.018.08