

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

Published: 21-01-2008

Last updated: 07-05-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Central nervous system vascular disorders
<b>Study type</b>	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 acetylsalicylic acid 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**

### **Public**

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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  $\geq 18$  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  $< 100 \times 10^9/l$ )
- \* known contra-indications to ASA treatment (e.g. previous adverse reaction to ASA)
- \* Known anticoagulants 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**

CCMO

**ID**

NL15747.018.08