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

Gepubliceerd: 21-11-2006 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24653

Bron
Nationaal Trial Register

Verkorte titel
ARTIS

Aandoening

Re-occlussion in ischemic stroke.

Ondersteuning

Primaire sponsor: Netherlands Heart Foundation (Nederlandse Hartstichting).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Age ≥ 18 years

3. Written informed consent is obtained

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-07-2008
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-11-2006
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	ID
NTR-new	NL809
NTR-old	NTR822
Ander register	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
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.