Paracetamol (Acetaminophen) in Stroke 2 (PAIS 2): A randomized clinical trial to investigate the effect of high-dose paracetamol in patients with acute stroke and a body temperature of 36,5°C or above.

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We hypothesize that treatment of patients with acute ischemic or hemorrhagic stroke and a body temperature of 36,5°C or above with paracetamol in a daily dose of 6 g for three consecutive days, leads to improved functional outcome. At least 50%...

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

Samenvatting

ID

NL-OMON24724

Bron
NTR

Verkorte titel
PAIS 2

Aandoening

acute stroke, cerebral infarction, intracraniel hemorrhage, acetaminophen, body temperature, inflammation, functional outcome

herseninfarct, hersenbloeding, paracetamol, lichaamstemperatuur, inflammatie, functionele uitkomst

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A favorable outcome defined as improvement on the modified Rankin Scale (mRS) at 3 months from stroke onset.

Toelichting onderzoek

Achtergrond van het onderzoek

In the Paracetamol (Acetaminophen) in Stroke (PAIS) trial, a double-blind, placebo-controlled randomized clinical trial of 1400 patients with acute stroke, the paracetamol-treated patients (6 g daily, 3 days) showed more improvement on the modified Rankin scale (mRS) at 3 months, yet the difference was not statistically significant. In the 661 patients with a baseline body temperature of 36,5°C or above, treatment with paracetamol led to a larger decrease in temperature (0.30°C; 95% CI: 0.20-0.40), increased the odds of improvement (OR 1.43; 95% CI: 1.02-1.97) and was associated with a 7% (95% CI: 0-15%, p=0.06) absolute decrease in the risk of poor outcome. These findings need further study.

Doel van het onderzoek

We hypothesize that treatment of patients with acute ischemic or hemorrhagic stroke and a body temperature of 36,5°C or above with paracetamol in a daily dose of 6 g for three consecutive days, leads to improved functional outcome.

At least 50% of patients with acute stroke have a body temperature over 36,5°C. Increased body temperature is related to poor functional outcome. The risk of poor outcome may double with each degree Celsius increase in body temperature.

Onderzoeksopzet

1. Oktober 2010: first inclusion;

2. Juli 2014: final inclusion;

3. Oktober 2014: end of follow-up.

Onderzoeksproduct en/of interventie

Paracetamol or matching placebo will be administered 6 times daily for three consecutive days; the first 24 hours as suppositories of 1 g, or as 2 tablets of 500 mg per dosage (after swallowing difficulties have been excluded), from 24-72 hours as 2 tablets of 500 mg per dosage.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Clinical diagnosis of ischemic stroke or intracerebral hemorrhage, confirmed by CT or MRI scan within 24 hours after inclusion in the study;

2. A measurable deficit on the National Institutes of Health Stroke Scale (NIHSS);

3. The possibility to start treatment within 12 hours of symptom onset (for patients who

noticed symptoms when awaking from sleep, the time last seen well is taken as the time of onset of symptoms);

4. A body temperature of 36,5°C or higher;

5. Age of 18 years or older;

6. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A body temperature lower than 36.5°C;

2. A history of liver disease or alcohol abuse;

3. Liver enzymes (ASAT, ALAT, AP or gamma-GT) increased above twice the upper limit of normal values;

4. Allergy to paracetamol;

5. Death appearing imminent at the time of inclusion;

6. Any pre-stroke impairment that has led to dependency (modified Rankin scale (mRS)>2) and therefore interferes with the assessment of functional outcome.

Onderzoeksopzet

Opzet

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

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	1500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-06-2010
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	NL2239
NTR-old	NTR2365
Ander register	WHO UTN : U1111-1124-9185
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Den Hertog HM et al. The Paracetamol (Acetaminophen) In Stroke trial: a multicentre, randomised, placebo-controlled, phase III trial. Lancet Neurol. 2009 May;8(5):434-40.