Paracetamol (Acetaminophen) In Stroke.

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Early antipyretic therapy reduces the risk of death or dependency in patients with acute stroke, even if they are normothermic

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

Samenvatting

ID

NL-OMON25645

Bron
Nationaal Trial Register

Verkorte titel
PAIS

Aandoening

stroke

Ondersteuning

Overige ondersteuning: PAIS is sponsored by the Netherlands Heart Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the dichotomized mRS (¡Ü2: good outcome, ¡Ý3: poor outcome) at 3 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Subfebrile temperature and fever in the acute phase of stroke are associated with large infarct volumes, high case fatality and poor functional outcome. A 1ºC rise in body temperature may double the odds of poor outcome in patients who are admitted within 12 hours from onset of symptoms. Two pilot studies showed that high-dose paracetamol induces a decrease in body temperature of 0.3-0.4¡ãC in patients with acute ischemic stroke, even if they are normothermic. This effect occurs within 4 hours after the start of treatment. The purpose of PAIS is to assess whether this decrease in body temperature translates into better clinical outcomes.

Doel van het onderzoek

Early antipyretic therapy reduces the risk of death or dependency in patients with acute stroke, even if they are normothermic

Onderzoeksproduct en/of interventie

Treatment with high dose paracetamol (6 g/day) or placebo will start within 12 hours after onset of symptoms, and continue for 3 days.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Clinical diagnosis of acute stroke

2. Possibility to start treatment within 12 hours from onset

3. Brain CT or MRI within 24 hours

4. Age 18 years or older

5. Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A body temperature lower than 36 degrees Celsius or higher than 39 degrees Celsius

2. A history of liver disease

3. Alcohol abuse

4. Liver enzymes increased above twice the upper limit of normal

5. Allergy to paracetamol

6. Significant pre-stroke impairment (³3 on the modified Rankin Scale (mRS))

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2003
Aantal proefpersonen:	2500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-08-2006
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	NL740
NTR-old	NTR750
Ander register	: N/A
ISRCTN	ISRCTN74418480

Resultaten

Samenvatting resultaten

PAPAS, Dippel, van Breda et al., Stroke 2001
PISA, Dippel, van Breda et al., BMC Cardiovascular Disorders, 2003
PAIS protocol, van Breda, van der Worp et al., BMC Cardiovascular Disorders, 2005