

Paracetamol (Acetaminophen) In Stroke

Submission date 06/11/2002	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 06/11/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/02/2021	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR750

Study information

Scientific Title

Paracetamol (Acetaminophen) In Stroke

Acronym

PAIS

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute stroke

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Paracetamol

Primary outcome(s)

Dichotomised mRS (less than or equal to two: good outcome, more than or equal to six: poor outcome) at three months.

Key secondary outcome(s)

1. Score on the Barthel index after two weeks
2. Body temperature after 24 hours of treatment
3. EuroQol-5D instrument at three months

Completion date

01/09/2008

Eligibility**Key inclusion criteria**

1. Clinical diagnosis of acute stroke
2. Possibility to start treatment within 12 hours from onset
3. Brain Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) within 24 hours
4. Age 18 years or older
5. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

1400

Key exclusion criteria

Body temperature lower than 36°C or higher than 39°C

A history of liver disease

Alcohol abuse

1. Liver enzymes increased above twice the upper limit of normal
2. Allergy to paracetamol
3. Significant pre-stroke impairment (more than three on the modified Rankin Scale [mRS])

Date of first enrolment

01/05/2003

Date of final enrolment

01/09/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Charity

Funder Name

Netherlands Heart Foundation; known as 'Early antipyretic therapy in acute stroke trial' (ref 2002B148) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009	18/02/2021	Yes	No
Protocol article	protocol in Dutch	04/10/2003		Yes	No
Protocol article	protocol in English	19/08/2005		Yes	No
Protocol article	protocol correction	04/11/2008		Yes	No