ISRCTN74418480 https://doi.org/10.1186/ISRCTN74418480

Paracetamol (Acetaminophen) In Stroke

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure

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

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

Overall study start date
01/05/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2500

Total final enrolment
1400

Key exclusion criteria
Abody temperature lower than 36¡ãC or higher than 39¡ãC
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)

Sponsor details
Department of Neurology
PO Box 2040
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Sponsor type
Government

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
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
Results article	results	01/05/2009	18/02/2021	Yes	No