

# Paracetamol (Acetaminophen) In Stroke

<b>Submission date</b> 06/11/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/11/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/02/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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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### Contact details

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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**

A 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)

**Sponsor details**

Department of Neurology

PO Box 2040

Rotterdam

Netherlands

3000 CA

**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?
<a href="#">Protocol article</a>	protocol in Dutch	04/10/2003		Yes	No
<a href="#">Protocol article</a>	protocol in English	19/08/2005		Yes	No
<a href="#">Protocol article</a>	protocol correction	04/11/2008		Yes	No
<a href="#">Results article</a>	results	01/05/2009	18/02/2021	Yes	No