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# The effect of paracetamol (acetaminophen) and ibuprofen on body temperature in acute stroke: a phase II double-blind randomised placebo-controlled trial

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| **Submission date**<br>15/02/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>15/02/2002 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>06/09/2007 | **Condition category**<br>Circulatory System | [_] Individual participant data |

**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
N/A

# Study information

### Scientific Title

### Acronym
PISA

### Study objectives
To study the effect of high-dose ibuprofen and to confirm the previously observed reducing effect of high-dose paracetamol on body temperature, and to study their safety in normothermic and subfebrile patients with acute ischaemic stroke.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The medical ethics committees of the three hospitals have approved this protocol.

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Stroke

### Interventions
1. Paracetamol 6 g daily, for 5 days
2. Ibuprofen 2.4 g daily, for 5 days
3. Placebo for 5 days

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Paracetamol (acetaminophen), ibuprofen

### Primary outcome measure
Body temperature at 24 hours from start of treatment.

### Secondary outcome measures
1. Change in baseline temperature at 1 and 5 days from start of treatment
2. Time with elevated body temperature (greater than 37.0°C) (area under the curve) during the first 24 hours and the first five days

Tertiary outcomes:
Functional outcome at one month, as determined by the scores on the modified Rankin Scale (mRS) and Barthel Index (BI).

### Overall study start date
01/12/2000

### Completion date
31/12/2001

## Eligibility

### Key inclusion criteria
1. An acute ischaemic anterior circulation stroke
2. A body temperature greater than 36.0°C or less than 39.0°C
3. A CT scan that is compatible with acute ischaemic stroke
4. A focal deficit without rapid improvement
5. A possibility to start treatment within 24 hours after stroke onset

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
75

### Key exclusion criteria
1. Severe aphasia, defined as an aphasia score of 2 or 3 on the National Institutes of Health Stroke Scale (NIHSS)
2. Treatment with an non-Steroidal Anti-Inflammatory Drug (NSAID) deemed necessary
3. Hypersensitivity to ibuprofen or paracetamol

4. (Chronic) liver failure or cirrhosis
5. (Chronic) renal failure
6. History of alcohol abuse
7. Active gastric ulcer disease or a history of peptic ulceration or gastro-intestinal haemorrhage in the preceding year
8. Colitis ulcerosa
9. Pregnancy
10. Use of corticosteroids
11. A severe concomitant medical condition that could affect the assessment of the effect of the study medication on temperature
12. Residual neurological impairment resulting from a previous stroke that may hamper the assessment of functional outcome
13. Death appearing imminent
14. No informed consent given

### Date of first enrolment
01/12/2000

### Date of final enrolment
31/12/2001

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Dept of Neurology**
Rotterdam
Netherlands
3000 CR

## Sponsor information

### Organisation
Erasmus Medical Center (The Netherlands)

### Sponsor details
P.O. Box 1738
Rotterdam
Netherlands
3000 DR

### Sponsor type
Hospital/treatment centre

### Website
http://www.erasmusmc.nl/content/englishindex.htm

### ROR
https://ror.org/018906e22

## Funder(s)

### Funder type
Research organisation

### Funder Name
Rotterdam Neurovascular Research Foundation (Stichting Neurovasculair Onderzoek Rotterdam) (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 | 27/03/2002 | | Yes | No |
| Results article | Results | 06/02/2003 | | Yes | No |