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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

Submission date
15/02/2002

Recruitment status
No longer recruiting

Registration date
15/02/2002

Overall study status
Completed

Last Edited
06/09/2007

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Body temperature at 24 hours from start of treatment.

Key secondary outcome(s)
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).

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

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

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	06/02/2003		Yes	No
Protocol article	Protocol	27/03/2002		Yes	No