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A randomised controlled trial of combination versus single antipyretic treatment in febrile children

Submission date 18/02/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/02/2005	**Overall study status** Completed	
Last Edited 19/02/2008	**Condition category** Signs and Symptoms	

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

Study objectives
Our study hypothesis is that combined antipyretic therapy (a single dose of 10 mg/kg ibuprofen followed by a single dose of 15 mg/kg of acetaminophen after 4 hours) is more effective than ibuprofen (10 mg/kg) followed by placebo, in reducing the temperature of children with high fever.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Fever

Interventions
1. Experimental group: A single dose (10 mg/kg) of Ibuprofen at zero time, followed by a single dose (15 mg/kg) of Acetaminophen at time = 4 hours
2. Control group: A single dose (10 mg/kg) of Ibuprofen at time zero, followed by a single dose (15 mg/kg) of Placebo at time = 4 hours
3. Rectal temperature recordings at baseline and at time = 4, 5, 6, 7 and 8 hours

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary endpoint of this study is the proportion of children in each group, with body temperature of 37.8°C or less at time 6 hours.

Secondary outcome measures
Secondary endpoints include the proportion of children in each group, with body temperarures of 37.8°C and below, at times 7 and 8 hours, and the change in hourly temperature from baseline, at times 4, 5, 6, 7, 8 hours.
The proportion of patients in each group with any immediate adverse effect (within 24 hours from administration) that may be related to either drug, such as gastrointestinal bleed, hypothermia or others.

Overall study start date
26/11/2002

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Age between 6 months and 14 years
2. Rectal temperature greater than or equal to 38.8°C
3. Consent of treating physician
4. Consent of parent(s) and child if old enough to give consent (greater than 7 years)
5. No antipyretic intake for 8 hours prior to enrolment

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
14 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Presence of concurrent hepatic or renal disease
2. Chronic and/or serious disease such as malignancy, septic shock, malabsorption syndromes etc.
3. Any condition that may interfere with the absorption of the investigational drugs such as gastritis, diarrhoea, ileus etc.

4. Hypersensitivity to acetaminophen or ibuprofen
5. Bleeding disorder or tendency
6. Asthma

Date of first enrolment
26/11/2002

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Lebanon

Study participating centre
American University of Beirut Medical Center
Beirut
Lebanon
113-6044/C8

Sponsor information

Organisation
American University of Beirut (Lebanon)

Sponsor details
Faculty of Medicine, Medical Practice Plan
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Sponsor type
University/education

ROR
https://ror.org/04pznsd21

Funder(s)

Funder type
University/education

Funder Name
American University of Beirut (Lebanon) - Medical Practice Plan of the Faculty of Medicine (ref: DCR 114170-034120)

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?
Results article	Results	04/03/2006		Yes	No