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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
18/02/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/02/2005	Completed	[X] Results		
Last Edited 19/02/2008	Condition category Signs and Symptoms	[] Individual participant data		
17/02/2000	Digita and Dymptoms			

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

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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.

Completion date

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

14 years

Sex

All

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)

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

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