# 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	Condition category	Individual participant data		
19/02/2008	Signs and Symptoms			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Mona Nabulsi

#### Contact details

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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 Riyad El-Solh Beirut Lebanon 11-02-36 +961 (0)1 350000 resdean@aub.edu.lb

## 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