

# A randomised controlled trial of rectal versus oral acetaminophen antipyresis in children

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<b>Registration date</b> 10/03/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2007	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> 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

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

**Study objectives**

This randomised, double-dummy and placebo controlled study was conducted to compare the antipyretic efficacies of two different rectal doses of acetaminophen: 15 mg/kg and 35 mg/kg to that of a standard oral dose of 15 mg/kg, over a six-hour period, to allow detection of late antipyresis that may occur with rectal acetaminophen. The results of this study will provide further evidence on the comparative antipyretic efficacy of different doses of rectal acetaminophen versus the standard oral one.

Our study hypothesis was that a single dose of 15 mg/kg oral acetaminophen is more effective than either 15 mg/kg or 35 mg/kg rectal acetaminophen, in reducing the temperature of febrile children.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Institutional Review Board and the Ethics Committee at the American University of Beirut, as well as the Board of the Middle East Hospital, approved this study.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Fever

### **Interventions**

Group 1: A single dose of oral acetaminophen (15 mg/kg) plus placebo rectal suppository (size equivalent to a 35 mg/kg rectal acetaminophen suppository)

Group 2: A single dose of oral placebo (equivalent to a 15 mg/kg oral acetaminophen) plus a rectal suppository containing 15 mg/kg acetaminophen and 20 mg/kg placebo.

Group 3: A single dose of oral placebo as in group 2 plus a rectal suppository of 35 mg/kg acetaminophen.

Rectal temperature readings at baseline and hourly for a total of 6 hours.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Acetaminophen

### **Primary outcome(s)**

Time to maximum antipyresis following administration of a single dose of acetaminophen.

**Key secondary outcome(s))**

Secondary outcomes included the temperatures at one, two, three, four, five, and six hours from administration and possible side effects such as hypothermia.

**Completion date**

30/09/2002

**Eligibility****Key inclusion criteria**

1. Age between 6 months and 13 years
2. Rectal temperature greater than or equal to 38.5 °C
3. Consent of treating physician
4. Written consent of parent and oral consent of child if older than 10 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**

13 years

**Sex**

All

**Key exclusion criteria**

1. Presence of concurrent or previous hepatic disease
2. Chronic and/or serious disease such as malignancy, septic shock, malabsorption syndromes etc.
3. Any condition interfering with the absorption of oral or rectal acetaminophen such as vomiting or severe diarrhoea, ileus, rectal bleeding etc.
4. Hypersensitivity to acetaminophen

**Date of first enrolment**

01/11/2000

**Date of final enrolment**

30/09/2002

**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 (grant ref: AUB A/C 686056)

## 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?
<a href="#">Results article</a>	Results	06/09/2005		Yes	No