ISRCTN11886401 https://doi.org/10.1186/ISRCTN11886401

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

Submission date 04/03/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/03/2005	**Overall study status** Completed	
Last Edited 20/12/2007	**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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/11/2000

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

Age group
Child

Lower age limit
6 Months

Upper age limit
13 Years

Sex
Both

Target number of participants
48

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)

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

Website
http://www.aub.edu.lb/

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

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	06/09/2005		Yes	No