Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of usual versus high-dose rectal Acetaminophen in the treatment of febrile children refers to 17-Sharivar Hospital of Rasht- Iran, 2008-9.

Protocol summary

Summary

This study is designed to compare the antipyretic effectiveness of 15 and 30 mg/kg dosages of rectal Acetaminophen in febrile children. Through this randomized controlled trial, 80 patients aged between 6 months and 6 years with rectal fever more than 39˚ Celsius refers to 17 Shahrivar Hospital of Rasht, Iran will be studied. The patients will be randomly assigned into one of two groups. First group (N= 40 cases) will receive 15 mg/kg and the second group (N= 40 cases) will receive 30 mg/kg Acetaminophen rectally. Then, the body temperature will be assessed at the end of the first and third hour and will be compared between two groups.

General information

Acronym

Comparison of usual versus high-dose rectal Acetaminophen

IRCT registration information

IRCT registration number: **IRCT138806182438N1**
Registration date: **2010-03-01, 1388/12/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-03-01, 1388/12/10

Registrant information

Name

Houman Hashemian

Name of organization / entity

Guilan University of medical sciences- Medical faculty- 17 Shahrivar hospital

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9061

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hashemian@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

1998-09-23, 1377/07/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of usual versus high-dose rectal Acetaminophen in the treatment of febrile children refers to 17-Sharivar Hospital of Rasht- Iran, 2008-9.

Public title

Comparison of usual versus high-dose rectal Acetaminophen in the treatment of febrile children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 6 months and 6 years, rectal temperature 39- 40.5ºc, No presence of any of the following conditions: gastroenteritis in the 24 hours prior to the study, any medical or surgical condition that precluded rectal drug administration, acute or chronic hepatic disease, rectal bleeding, malabsorption syndromes, acute or chronic renal disease with the

exception of urinary tract infection, chronic metabolic disease, chronic neurological disease that may affect central thermoregulation, Febrile convulsion in the previous 6 hours, cancer, immune suppression, sepsis, critical medical status, Antipyretic administration in the previous 8 hours, Antibiotic administration within 12 hours prior to the initiation of the study until 3 hours afterwards, or known allergy to Acetaminophen Exclusion criteria: Ejection of Acetaminophen suppository within 30 minutes after administration, Development of allergy to Acetaminophen

Age
To **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Faculty (Vice-chancellor of research, Guilan University of Medical Sciences-

Street address
Medical Faculty (Vice-chancellor of research)- Guilan University of Medical Sciences, Rasht, Guilan, Iran

City
Rasht

Postal code

Approval date
2008-09-14, 1387/06/24

Ethics committee reference number
473

Health conditions studied

1

Description of health condition studied
Fever in children

ICD-10 code
R50.9

ICD-10 code description
Fever, unspecified

Primary outcomes

1

Description
Rectal Temperature

Timepoint
One and three hour after acetaminophen administration

Method of measurement
Rectal digital thermometer- Microlife

Secondary outcomes

empty

Intervention groups

1

Description
Acetaminophen, 30mg/kg , suppositiry, single dose at the initiation of fever

Category
Treatment - Drugs

2

Description
Acetaminophen, 15mg/kg , suppositiry, single dose at the initiation of fever

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
17 Shahrivar Hospital of Rasht

Full name of responsible person
Dr. Houman Hashemian, M.D.

Street address
17 Shahrivar Hospital- Namjoo st., Rasht, Iran

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person
Houman Hashemian

Street address
17 Shahrivar Hospital, Namjoo st., Rasht, Iran
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Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences- Medical Faculty- 17 Shahrivar Hospital of Rasht
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Person responsible for updating data

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Other areas of specialty/work
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Email
hashemian@gums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty