Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of intravenous Acetaminophen, Diclofenac suppository and Acetaminophen suppository in febrile hospitalized children

Protocol summary

Summary

This study is designed to compare the antipyretic effectiveness of intravenous and rectal Acetaminophen and rectal Diclofenac in febrile children. Through this randomized controlled trial, 120 patients aged between 1 and 6 years with rectal fever more than 38˚ Celsius refer to Beheshti Hospital of Kashan, Iran will be studied. Inclusion criteria included: Children aged 1 to 6 years admitted in Beheshti Hospital with rectal temperature over 38 degrees. Exclusion criteria included: The use of anti pyretic drug before admission; diarrhea; drug intolerance; using techniques such as sponge. The patients will be randomly assigned into one of three groups. First group (N= 40 cases) will receive 15 mg/kg Acetaminophen rectally and the second group (N= 40 cases) will receive 10 mg/kg Acetaminophen (IV) and the third group (N= 40 cases) will receive 1 mg/kg Diclofenac rectally. Then, the body temperature will be assessed at the end of the first hour and will be compared between three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101711145N1**
Registration date: **2012-11-10, 1391/08/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-10, 1391/08/20

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous Acetaminophen, Diclofenac suppository and Acetaminophen suppository in febrile hospitalized children

Public title

Comparison of intravenous Acetaminophen, Diclofenac suppository and Acetaminophen suppository in febrile hospitalized children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children admitted in Beheshti Hospital; rectal temperature over 38 degrees; children aged 1 to 6 years. Exclusion criteria: The use of anti pyretic drug before admission; diarrhea; drug intolerance; using techniques such as sponge.

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

5th Km of Ghotbe Ravandi Bulv.

City

Kashan

Postal code

Approval date

2012-10-17, 1391/07/26

Ethics committee reference number

29/5/1/2742/پ

Health conditions studied

1

Description of health condition studied

Fever

ICD-10 code

R50.9

ICD-10 code description

Fever, unspecified

Primary outcomes

1

Description

Rectal Temperature

Timepoint

One hour after Acetaminophen and Diclofenac perception

Method of measurement

Rectal digital thermometer- Microlife

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Acetaminophen, 10mg/kg , intravenous, single dose at the initiation of fever

Category

Treatment - Drugs

3

Description

Diclofenac, 1mg/kg , suppository, single dose at the initiation of fever

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Dr. Mehrdad Hossein pour

Street address

5th Km of Ghotbe Ravandi Bulv.

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

5th Kilometer Ghotbe Ravandi Bulv.Kashan University of Medical Sciences

City

kashan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr.Mohammad Reza Sharif
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Assistant Professor, Pediatric Infectious Diseases Subspecialist
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Person responsible for updating data

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Name of organization / entity
Kashan University of Medical Sciences
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Assistant Professor, Pediatric Infectious Diseases Subspecialist
Other areas of specialty/work
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Postal code
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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