

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparing effect of Indomethacin with Diclofenac and Acetaminophen suppositories in reducing the fever in children

Protocol summary

Summary

This study is designed to compare the antipyretic effectiveness of Indomethacin with Diclofenac and Acetaminophen suppositories in children. Through this randomized controlled trial, 150 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= 50 cases) will receive 1 mg/kg Indomethacin rectally and the second group (N= 50 cases) will receive 1 mg/kg Diclofenac rectally and the third group (N= 50 cases) will receive 10 mg/kg Acetaminophen 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: **IRCT2013021711145N4**

Registration date: **2013-03-10, 1391/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-10, 1391/12/20

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of Indomethacin with Diclofenac and Acetaminophen suppositories in reducing the fever in children

Public title

Comparing effect of Indomethacin with Diclofenac and Acetaminophen suppositories in reducing the fever in 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: **150**

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 Kilometer, Ghotbe Ravandi Bulv, Kashan

City

Kashan

Postal code

Approval date

2013-02-17, 1391/11/29

Ethics committee reference number

4246/1/5/29/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 Indomethacin, Acetaminophen and

Diclofenac perception

Method of measurement

Rectal digital thermometer- Microlife

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

3

Description

Acetaminophen, 10mg/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.Mohammad Reza Sharif

Street address

Beheshti Hospital, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

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

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

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

Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

Other areas of specialty/work

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Full name of responsible person

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Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

Other areas of specialty/work

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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