# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

**Street address**

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**Web page address**

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## Person responsible for updating data

**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**

**Street address**

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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*