

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

###### 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

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  
**Position**  
Assistant Professor, Pediatric Infectious Diseases  
Subspecialist  
**Other areas of specialty/work**  
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Kashan  
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sharif\_m@kaums.ac.ir  
**Web page address**

## 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**  
Assistant Professor, Pediatric Infectious Diseases  
Subspecialist  
**Other areas of specialty/work**  
**Street address**  
**City**  
**Postal code**  
**Phone**  
**Fax**  
**Email**  
**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*