Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Antipyretic effect of intravenous ibuprofen compared to oral ibuprofen and rectal diclofenac in children

Protocol summary

Summary

This study is designed to compare the antipyretic effect of intravenous ibuprofen with oral ibuprofen or diclofenac suppositoriy in children. Through this randomized controlled trial, 90 children admitted in Shahid Beheshti Hospital of Kashan will be studied. Inclusion criteria included: Children aged 1 to 6 years with axillary 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 to three groups. First group (N= 30 cases) will receive 5 mg/kg intravenous ibuprofen and the second group (N= 30 cases) will receive 5 mg/kg oral ibuprofen and the third group (N= 30 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: **IRCT2014052711145N10**
Registration date: **2014-08-12, 1393/05/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-08-12, 1393/05/21

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

2014-08-23, 1393/06/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antipyretic effect of intravenous ibuprofen compared to oral ibuprofen and rectal diclofenac in children

Public title

Antipyretic effect of intravenous ibuprofen compared to oral ibuprofen or rectal diclofenac in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children admitted in Shahid Beheshti Hospital; axillary temperature over 38 degrees; 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

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Postal code

Approval date

2014-08-06, 1393/05/15

Ethics committee reference number

29.5.1.2150

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

Axillary temperature

Timepoint

One hour after drug perception

Method of measurement

Mercury thermometer

Secondary outcomes

empty

Intervention groups

1

Description

Ibuprofen, 5 mg/kg , intravenous, single dose at the initiation of fever control

Category

Treatment - Drugs

2

Description

Ibuprofen, 5 mg/kg , oral, single dose at the initiation of fever control

Category

Treatment - Drugs

3

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr.Mohammad Reza Sharif

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd, Kashan, Iran

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, Ghotbe Ravandi Blvd, Kashan, Iran

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

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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