Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of rectal diclofenac and high dose rectal acetaminophen on fever among children

Protocol summary

Study aim
To comparing high-dose rectal acetaminophen and diclofenac suppository in controlling children's fever.

Design
The present study is a double blind clinical trial study. Patients will be randomly divided into two groups of 45 children. All children aged 1 to 6 years who meet the inclusion criteria will be included in the study based on 22 random blocks of size 4 and one block of size 2 in a sealed envelope. The name of children will be expelled from the envelopes gradually. The patient is not aware of the type of medication he receives, nor is the person who measures the temperature.

Settings and conduct
The present study is carried out at 17th Shahrivar Hospital in Rasht- Iran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 1 to 6 years old; at least 10 kg weight; fever between 39-40.5 ° C rectal temperature lasted for less than 4 days. Non-inclusion criteria: History of chronic disease; recent use of antipyretic drugs or antibiotics

Intervention groups
Intervention group 1: These children will receive high dose acetaminophen suppositories at a dose of 30mg / kg. Intervention group 2: These children will receive diclofenac suppositories at a dose of 1mg / kg.

Main outcome variables
The patient's rectal temperature after one and three hours of intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090909002438N3**
Registration date: **2019-07-04, 1398/04/13**
Registration timing: **registered_while_recruiting**
Last update: **2019-07-04, 1398/04/13**
Update count: **0**

Registration date
2019-07-04, 1398/04/13

Registrant information

Name
Houman Hashemian

Name of organization / entity
Guilan University of medical sciences- Medical faculty- 17 Shahrivar hospital

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Iran (Islamic Republic of)

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+98 13 3336 9061

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of rectal diclofenac and high dose rectal acetaminophen on fever among children

Public title
The effect of diclofenac on the treatment of fever in children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 1 to 6 years old at least 10 kg weight Fever between 39-40.5 ° C of rectal temperature lasted for less than 4 days

Exclusion criteria:

Diarrhea in the last 24 hours History of previous sensitivity to acetaminophen and diclofenac History of malignancy History of renal failure History of liver failure History of neurological disease or febrile convulsion within the past hour, or loss of consciousness or known vasculitis Use of antipyretic over the past 8 hours Use of antibiotics within the past 8 hours or 3 hours after the administration of the active antipyretic drug (acetaminophen or diclofenac) History of Hyper Reactive Airway Disease History of gastritis and peptic ulcer

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups of 45 children. All children aged 1 to 6 years who meet the inclusion criteria will be included in the study based on 22 random blocks of size 4 and one block of size 2 in a sealed envelope. The name of children will be expelled from the envelopes gradually.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the type of medication he receives, nor is the person who measures the temperature.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Guilan University of Medical Sciences

Street address

Vice-chancellor for Research, Guilan University of Medical Sciences, in front of 17 Shahrivar hospital, Shahid Siadati Street, Namjoo Street

City

Rasht

Province

Guilan

Postal code

4144654679

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.GUMS.REC.1397.504

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

Rate of patient temperature

Timepoint

Measure the temperature of the patients before, one and three hours after the intervention

Method of measurement

Digital rectal thermometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: These children will receive acetaminophen suppository at a dose of 30 mg / kg. The acetaminophen suppositories 125 and 325 mg are manufactured by Daroupakhsh Pharmaceutical MFG Co., Lot/Batch Number: 304 & 622, respectively. Based on the child’s weight, the suppositories will be cut off of length according to the required amount and will be weighted by a digital scale (Notebook series- Model: 1108-2 manufactured by Shenzhen Big Dipper Co., LTD., China); and then will be used. The rectal temperature of the patients will be measured before and then, one and three hours after the intervention, using the Beurer Digital Thermometer, FT15 / 1, manufactured by Beurer GmbH, Germany.

Category

Treatment - Drugs

2

Description
Intervention group: These children will receive diclofenac suppository at a dose of 1 mg / kg. The diclofenac suppositories 50 mg are manufactured by Daroupakhsh Pharmaceutical MFG Co., Lot/Batch Number: 873. Based on the child's weight, the suppositories will be cut off of length according to the required amount and will be weighted by a digital scale (Notebook series- Model: 1108-2 manufactured by Shenzhen Big Dipper Co., LTD., China); and then will be used. The rectal temperature of the patients will be measured before and then, one and three hours after the intervention, using the Beurer Digital Thermometer, FT15 / 1, manufactured by Beurer GmbH, Germany.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
17th Shahrivar Hospital
Full name of responsible person
Houman Hashemian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Shademan Nemati
Street address
Vice-chancellor for Research, Guilan University of Medical Sciences, in front of 17 Shahrivar hospital, Shahid Siadati Street, Namjoo Street
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research@gums.ac.ir
Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Houman Hashemian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Individual data related to primary outcome can be shared after making the data anonymous

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
Only available for people working in academic institutions.

Under which criteria data/document could be used
The use of data from this study is permitted for academic use and should be cited in the paper.

From where data/document is obtainable
Request only by email to researcher: hashemian@gums.ac.ir

What processes are involved for a request to access data/document
The request must be submitted with the full individual and academic information of the applicant. Then the case is presented to the research committee at the presence of all the researchers and the data will be sent if approved.

Comments