

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison antipyretic effect of Acetaminophen and Ibuprofen alone and together infant and children between 6 month and 10 years of age

Protocol summary

Summary

Background: Fever is a natural response to infection that annually hosts approximately 70 % of preschool children. Acetaminophen is widely used as an antipyretic drug with high efficiency and safety. Ibuprofen is one of the Propionic acid derivatives in which like acetaminophen. Use paracetamol plus Ibuprofen increasingly used to treat fever associated symptoms, but it is unclear whether the combination of the two is better than using each alone or not. The aim of this study is comparison of Acetaminophen and ibuprofen to control fever with the combination of both. According to a study conducted by Alastair D Hay and colleagues, 540 patients with fever higher than 38 entered to the study. The patients randomized into three groups to receive acetaminophen, ibuprofen and acetaminophen + ibuprofen. Before taking the drugs were measured fever and consequently after 2, 4 and 6 hours fever temperatures were measured. Information about each patient included age, sex, weight, temperature, duration of fever, antibiotics, acetaminophen or ibuprofen before you go to the doctor, appetite, sleep, activity of disease at diagnosis, history of asthma, a history of febrile seizures in the past, they will be excluded and patients will be enrolled who have previously received nothings. Information collected will be analyzed after entering in the SPSS program with one way Analysis of Variance and tukey test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120815706N1**
Registration date: **2014-01-28, 1392/11/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-28, 1392/11/08

Registrant information

Name

Noor Mohammad Noori

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 1342 5611

Email address

dr_noori_cardio@yahoo.com

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison antipyretic effect of Acetaminophen and Ibuprofen alone and together infant and children between 6 month and 10 years of age

Public title

Comparison antipyretic effect of Acetaminophen and Ibuprofen alone and together

Purpose

Treatment

Inclusion/Exclusion criteria

From all feverish children between 6 months to 10 years who presented to the emergency center for children of Ali ibn Abi Talib Hospital, those considered for study with fever above 38 as inclusion criteria. Children who need hospitalization, they are clinically dehydrated; history of intolerance, allergies and contraindications or drug use have chronic lung disease except asthma , cardiac, neurologic , hepatic and renal have and their parents ability to care for children at home may not be excluded.

Age

To **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **540**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences (ZaYMS)

Street address

Dr Hesabi Circle, ZaYMS Pardis

City

Zahedan

Postal code

Approval date

2012-09-27, 1391/07/06

Ethics committee reference number

91-1064

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

Fever

Timepoint

2, 4, 6 hours after consumption

Method of measurement

Using axillary thermometer method

Secondary outcomes

empty

Intervention groups

1

Description

Temperature of fever at the start for each group is considered as a control. It should be noted that all three groups before the intervention were similar in all respects. Then the group A we took acetaminophen of 120mg/5ml with dose 15 mg per kg of body weight every six hours for 24 hours.

Category

Treatment - Drugs

2

Description

In group B, ibuprofen of 100mg/5ml with dose of 10 mg per kg every six hours for 24 hours.

Category

Treatment - Drugs

3

Description

and in Group C acetaminophen dose of 15 mg per kg of body weight and ibuprofen at a dose of 10 mg per kg of body weight the body was given every six hours for 24 hours. Therefore, control considered at the time of entrance and intervention considered after entrance.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Dr Qasem Miri Aliabadi

Street address

Zahedan, Imam Ali Hospital

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of resaerch

Full name of responsible person

Vahideh Ghodrati

Street address

Zahedan, Imam Ali Hospital

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of resaerch

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

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Noor Mohammad Noori

Position

MD, Pediatrician

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Masoomah Ghanbari

Position

Expert for the center of Children health Center

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