Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Zahedan

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
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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