Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

analgesic effect of oral acetaminophen and ibuprofen in children with humerus supracondylar fracture

Protocol summary

Summary

The Objective of this study is to compare the analgesic effect of oral acetaminophen and ibuprofen in children with humerus supracondylar fracture. This study is design as a clinical trial. In this study children with supracondylar fracture will be enrolled. They will be divided into two groups regard to random block method. Children with supracondylar fractures will be enrolled the study and exclusion criteria are history of gastrointestinal (GI) bleeding or GI ulcers; low platelet count; renal disease; significant allergy for Acetaminophen or Ibuprofen and underlying chronic diseases. First group will receive Acetaminophen about 10 mg/kg every 4-6 hours (with maximum dose 400 mg) and the second one will receive 10/kg/day Ibuprofen in 3 or 4 divided dose. Patients' pain will be evaluated after 2, 4 and 12 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100811956N7**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Morteza Talebi Doluee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5312

Email address

talebidm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2017-06-15, 1396/03/25

Expected recruitment end date

2017-07-08, 1396/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

analgesic effect of oral acetaminophen and ibuprofen in children with humerus supracondylar fracture

Public title

Comparison the analgesic effect of oral acetaminophen and ibuprofen in children with humerus supracondylar fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Children with supracondylar fractures will be enrolled the study and exclusion criteria are history of gastrointestinal (GI) bleeding or GI ulcers; low platelet count; renal disease; significant allergy for Acetaminophen or Ibuprofen and underlying chronic diseases.

Age

To **18 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences ethical committee
Street address
Ghoreyshi Building, Daneshgah Strees, Mashhad
City
Mashhad
Postal code
Approval date
2016-05-26, 1395/03/06
Ethics committee reference number
IR.MUMS.fm.REC.237

Health conditions studied

1

Description of health condition studied
Fracture of lower end of humerus
ICD-10 code
S42.4
ICD-10 code description
Fracture of lower end of humerus

Primary outcomes

1

Description
Pain severity
Timepoint
2 hours, 4 hours and 12 hours
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Acetaminophen about 10 mg/kg every 4-6 hours (with maximum dose 400 mg)
Category
Treatment - Drugs

2

Description
10-20 mg/kg/day Ibuprofen in 3 or 4 divided dose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Dr. Morteza Talebi Doluee
Street address
Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Ghoreyshi Building, Daneshgah Strees, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad 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
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Morteza Talebi Doluee
Position
Assistant Professor of Emergency Medicine
Other areas of specialty/work
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Person responsible for updating data

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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