

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

A comparison between analgesic effect of intravenous acetaminophen vs intravenous morphine sulfate for isolated diaphysial long bone fractures

Protocol summary

Summary

We complete a randomized, double-blind study over 50 trauma patients who have isolated diaphysial long bone fracture in emergency department of Hasheminejad hospital in Mashhad, Iran. Inclusion criteria are the age between 15 and 60 years old; isolated diaphysial long bone fracture without decrease level of consciousness and without any other painful lesion. Participants are offered verbal information about the study as well as a written information sheet. Written informed consent is then obtained. The baseline data collected are: name, sex, age, body weight and the type of the fracture. Adverse reactions are recorded also at the end. Then one of two drugs-morphine sulfate or intravenous acetaminophen is chosen by the randomized block method for any patient. Before administration of chosen drug, our colleague (who is not aware of which drug has been chosen) asks the patient to determine his or her pain severity on the visual analogue scale. It should be noted the patient does not know that which drug has been chosen. Then the patient in morphine sulfate group receives 0.1 mg /kg of intravenous morphine sulfate by researcher. Again the researcher's colleague asks the patient to determine the pain level based on visual analogue scale 5 and 30 minutes after drug administration. Similarly the patient in acetaminophen group receives 15 mg /kg of intravenous acetaminophen by researcher and is asked by researcher's colleague to determine the pain severity based on visual analogue scale 5 and 30 minutes after injection. Finally, data will be compared and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012123111956N1**

Registration date: **2014-11-12, 1393/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-12, 1393/08/21

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

Mashhad University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between analgesic effect of intravenous acetaminophen vs intravenous morphine sulfate for isolated diaphysial long bone fractures

Public title

A comparison between analgesic effect of intravenous acetaminophen vs intravenous morphine sulfate for bone fractures

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion: dyaphisial fracture of long bone; no decrease level of consciousness; age between 15 to 60 years old.
 Exclusion criteria: decrease level of consciousness; any history of renal or hepatic disease; any other painful lesion; any history of opium addiction.

Age
 From **15 years** old to **60 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **50**

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
 Mashhad University of Medical Sciences
Street address
 Ethics Committee, Ghoreishi building, Daneshgah ave.
City
 Mashhad
Postal code
Approval date
 2012-10-27, 1391/08/06
Ethics committee reference number
 910391

Health conditions studied

1

Description of health condition studied
 Long bone fracture
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Pain decrease
Timepoint
 Before analgesic administration and 5 and 30 minutes after analgesic administration
Method of measurement
 Visual analoge scale

Secondary outcomes

1

Description
 Nausea and vomiting
Timepoint
 30 minutes after analgesic administration
Method of measurement
 Questionnaire

Intervention groups

1

Description
 We administer intravenous acetaminophen 15 mg/kg for the first group of patients with long bone fracture.
Category
 Treatment - Drugs

2

Description
 We administer morphine sulfate 0.1 mg/kg for second group of patients.
Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
 Shahid Hasheminejad hospital
Full name of responsible person
 Dr Morteza Talebi, emergency medicine specialist
Street address
 Aboureyhan bolv.
City
 Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

vice chancellor of research, Dr. Mohsen Tafaghodi

Street address

Vice chancellor of research, Ghoreishi building,
Daneshgah ave.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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. Bahram Zarmehri

Position

MD, resident of emergency medicine

Other areas of specialty/work

Street address

Department of emergency medicine, Emam Reza
hospital

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+98 51 3852 5312

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zarmehrib901@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Emergency Medicine, Mashhad
University of Medical Sciences

Full name of responsible person

Dr. Morteza Talebi

Position

Emergency medicine specialist, assistant professor of
emergency medicine

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Morteza Talebi

Position

Assistant professor of emergency medicine

Other areas of specialty/work

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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