

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Analgesic Effect of Intravenous Acetaminophen and Morphine Sulfate in Rib Fracture

Protocol summary

Summary

Rib fracture is one of the common causes of trauma disabilities in many events and the outcome of these patients are very extensive. Control and management of the pain in such patients is one of the most important challenges in emergency departments. In this double-blind study, 54 patients over 18 years of age, referred to Alzahra educational hospital with rib fracture, were entered. Patients were randomly categorized in two groups of morphine sulfate (0.1 milligram per kilogram of body weight) and IV acetaminophen (1gram), as single-dose infused in 100 cc normal saline. The pain severity was measured by Numeric Rating Scale on arrival and 30 minutes after drug administration. At least three scores reduction was reported as therapeutic success.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042812072N2**

Registration date: **2015-05-24, 1394/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-24, 1394/03/03

Registrant information

Name

Mehrdad Esmailian

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Analgesic Effect of Intravenous Acetaminophen and Morphine Sulfate in Rib Fracture

Public title

Analgesic Effect of Morphine and Acetaminophen

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : one or two rib fractures confirmed by chest radiography; normal level of consciousness (Glasgow Coma scale of 15); weight range between 60-100 kilogram; pain score > 4 centimeters based on Numeric Rating Scale; Exclusion criteria : background pulmonary problems; history of taking analgesic or opioid drugs; addiction; history of liver or kidney diseases; head trauma; pregnancy; respiratory arrest on arrival; repeated vomiting and nausea

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **54**

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

Isfahan University of Medical sciences

Street address

Azadi Ave.

City

Isfahan

Postal code

Approval date

2012-09-05, 1391/06/15

Ethics committee reference number

54561

Health conditions studied

1

Description of health condition studied

Rib fracture

ICD-10 code

S22.3

ICD-10 code description

Fracture of rib

Primary outcomes

1

Description

pain accuity

Timepoint

at start and 30 minute after intervention

Method of measurement

Numeric Rating Scale

Secondary outcomes

1

Description

vital signs

Timepoint

at start and 30 minute after intervention

Method of measurement

manomter and pulse checking

2

Description

O2 saturation

Timepoint

at start and 30 minute after intervention

Method of measurement

PulseOxymtery

3

Description

Drug Complications

Timepoint

at start and 30 minute after intervention

Method of measurement

History and physical examination

Intervention groups

1

Description

Intervention group treat with IV acetaminophen (1gram per kilogram of body weight, single-dose, and infused in 100 cc normal saline). If the pain will not relieved after the first 30 minutes, a rescue dose of morphine will inject by a trained physician, considered as a treatment failure.

Category

Treatment - Drugs

2

Description

Control group treat with morphine sulfate (0.1 milligram per kilogram of body weight, single-dose, and infuse in 100 cc normal saline). If the pain will not relieved after the first 30 minutes, a rescue dose of morphine will inject by a trained physician, considered as a treatment failure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mehrdad esmailian

Street address

Sofeh Blv.

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Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Reza Azizkhani

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Azadi Ave.

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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

Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Mehrdad Esmailian

Position

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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*