Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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

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Name of organization / entity

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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 con-sciousness (Glasgow Coma scale of 15); weight range be-tween 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 arriva;l 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.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Reza Azizkhani
Street address
Azadi Ave.
City
Isfahan
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
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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