

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of magnesium sulfate plus morphine versus morphine alone in long bone fractures pain alleviation in the emergency department

Protocol summary

Study aim

Comparison of the Effect of Intravenous Magnesium Sulfate-Morphine with Morphine on Pain Reduction in Extreme Limbs in Emergency Department

Design

This is a double-blind randomized clinical trial and patients and researchers are not aware of the type of intervention. In this study, 64 patients will participate. Randomly, each patient will be injected with morphine and magnesium sulfate or morphine. Time intervals of 0 - 15 - 30 - 45 and 60 minutes after drug injection are used to determine the severity of pain. During the study, the patient's condition is monitored by pulse oximeter, respiratory and pulse monitoring, blood pressure and knee motor reflex every 10 minutes.

Settings and conduct

This is a double-blind randomized clinical trial and patients and researchers are not aware of the type of intervention. In this study, 64 patients with isolated limb fractures referred to Golestan and Imam Khomeini hospitals in Ahvaz will participate. At admission, the patient's pain level is determined on an 11-point scale (0-10). Randomly, each patient will be injected with 0.1 mg / kg morphine and 30 mg / kg magnesium sulfate or 0.1 mg / kg morphine. Time intervals of 0 - 15 - 30 - 45 and 60 minutes after drug injection are used to determine the severity of pain. During the study, the patient's condition is monitored by pulse oximeter, respiratory and pulse monitoring, blood pressure and knee motor reflex every 10 minutes.

Participants/Inclusion and exclusion criteria

Organ fractures

Intervention groups

In the intervention group, each patient will be given 1.1 mg / kg morphine and 30 mg / kg magnesium sulfate. The control group will be injected with 1.1 mg / kg morphine.

Main outcome variables

Pain level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190617043913N1**

Registration date: **2020-01-30, 1398/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-30, 1398/11/10**

Update count: **0**

Registration date

2020-01-30, 1398/11/10

Registrant information

Name

Majid Fattah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3966

Email address

majid.fattah1357@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of magnesium sulfate plus morphine versus morphine alone in long bone fractures pain alleviation in the emergency department		61357-15794
Public title		Approval date
Comparison of magnesium sulfate plus morphine versus morphine alone in long bone fractures pain alleviation in the emergency department		2019-04-06, 1398/01/17
Purpose		Ethics committee reference number
Treatment		IR.AJUMS.REC.1398.143
Inclusion/Exclusion criteria		Health conditions studied
Inclusion criteria:		<u>1</u>
Long bone fracture		Description of health condition studied
Exclusion criteria:		Long fractures
Cardiovascular disease Pregnancy Drug addiction		ICD-10 code
Reduced alertness alcohol consumption		S22.4
Age		ICD-10 code description
From 15 years old to 65 years old		Multiple fractures of ribs
Gender		Primary outcomes
Both		<u>1</u>
Phase		Description
3		Pain
Groups that have been masked		Timepoint
- Participant - Investigator		Patient pain scores at 0 - 15 - 30 - 45 and 60 minutes after drug administration
Sample size		Method of measurement
Target sample size: 64		11 numeric grading scale (0-10)
Randomization (investigator's opinion)		Secondary outcomes
N/A		<u>1</u>
Randomization description		Description
Blinding (investigator's opinion)		Breath rate
Double blinded		Timepoint
Blinding description		Every 10 minutes
The study is double-blind. Patients and researchers are not aware of the type of group.		Method of measurement
Placebo		Pulse Oximeter
Not used		<u>2</u>
Assignment		Description
Parallel		Pulse rate
Other design features		Timepoint
Secondary Ids		Every 10 minutes
empty		Method of measurement
Ethics committees		Pulse Oximeter
<u>1</u>		<u>3</u>
Ethics committee		Description
Name of ethics committee		Blood pressure
Ethics committee of Ahvaz Jundishapur University of Medical Sciences		Timepoint
Street address		Every 10 minutes
Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences		Method of measurement
City		Barometer
Ahvaz		<u>4</u>
Province		Description
Khouzestan		Knee-jerk reflex
Postal code		

Timepoint

Every 10 minutes

Method of measurement

Reflex hammer

Phone

+98 61 3221 6104

Email

himam@ajums.ac.ir

Intervention groups**1****Description**

Intervention group: Each patient will be given 1.1 mg / kg morphine and 30 mg / kg magnesium sulfate.

Category

Treatment - Drugs

2**Description**

Control group: Will be injected with 1.1 mg / kg morphine.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Meisam Moezzi

Street address

Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

33118- 61357

Phone

+98 61 3374 3001

Fax

+98 61 3374 3030

Email

golestanhospital@ajums.ac.ir

2**Recruitment center****Name of recruitment center**

Imam khomeini hospital

Full name of responsible person

Sasan Moogahi

Street address

Azadegan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

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

Vice-Chancellor in Research Affairs, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Golestan Blv

City

Ahvaz

Province

Khouzestan

Postal code

15794- 61357

Phone

+98 61 3336 7543

Email

info@ajums.ac.ir

Grant name**Grant code / Reference number**

U-98032

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

Yes

Title of funding source

Vice-Chancellor in Research Affairs, Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Fattah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Golestan hospital, farvardin avenue, golestan street,ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-33118

Phone

+98 61 3374 3966

Fax

Email

majid.fattah1357@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Meisam Moezzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Golestan Blvd., Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

15794- 61357

Phone

+98 61 3336 7543

Email

meisam.moezzi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Fattah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Golestan hospital, farvardin avenue, golestan street,ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

33118- 61357

Phone

+98 61 3374 3966

Fax

Email

majid.fattah1357@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable