

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the analgesic effect of nebulized ketamine versus intravenous morphine in controlling acute pain in patients coming to the emergency department; A randomized controlled clinical trial.

Protocol summary

Study aim

Comparison of analgesic effect of nebulized ketamine versus intravenous morphine in patients coming to the ER with acute pain.

Design

Randomized, controlled, double blinded clinical trial, phase 3 designed for 84 patients. Randomization performs with block randomiation.

Settings and conduct

This study will be performed on patients coming to the Emergency room of Golestan hospital of Ahvaz, complaining of acute pain. The ER doctor will order nebulized Ketamine and infusion of normal saline serum in the case group and intravenous Morphine and nebulized sterile water in the control group. The researcher and the patient don't have any information about the treatment. After the patient got the analgesic drug, the researcher will ask about the level of the pain in decided minutes.

Participants/Inclusion and exclusion criteria

The condition to enter the study consists of the patients coming to the ER with acute pain greater than 7 out of 10 estimated by visual analogue scale. The conditions not to enter the study are; having mental illness mentioned by the patient; head trauma; ischemic heart disease; acute heart failure; respiratory distress; systolic blood pressure higher than 180 mmHg or less than 90 mmHg; asthma; high intracranial pressure; pregnancy; addiction; inability to describe pain; severe pain and need to use more than one dose of the drugs or need to change the drug; using analgesic drug before admission or history of allergy to ketamine or morphine.

Intervention groups

Patients with acute pain coming to the emergency department.

Main outcome variables

Pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220418054586N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **retrospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

Sahar Gholamzaheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 843 2046

Email address

sahar.ghz97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-12, 1401/07/20

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effect of nebulized ketamine versus intravenous morphine in controlling acute pain in patients coming to the emergency department; A randomized controlled clinical trial.

Public title

Comparison of analgesic effect of nebulized Ketamine versus intravenous Morphine in acute pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute pain in patients referred to the ER with a Visual analog scale (VAS) equivalent to or greater than 7 out of 10

Exclusion criteria:

Having a mental illness mentioned by the patient Head trauma Ischemic heart disease Acute heart failure Respiratory distress Systolic blood pressure greater than 180 mmHg or less than 90 mmHg Asthma High intracranial pressure Pregnancy Addiction Inability to describe the pain Using other analgesics before admission History of being allergic to Ketamine or Morphine or any contraindication of using these drugs

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the decided drug orders will be written on separate sheets to a certain number and then they will be placed in sealed envelopes and randomly numbered. Then the pockets will be offered to the emergency department doctor so that he can order the analgesic drug based on the order of each pocket. The researcher has to record the patient's name in a separate table along with the number of the pocket and after concluding the data collection, this table will be checked and compared to the numbers and names written on each pocket.

Blinding (investigator's opinion)

Double blinded

Blinding description

Behind the researcher confirms the inclusion criteria and randomly chooses the sample, the patient will be presented to the emergency department doctor to enter the study. The researcher offers the doctor a pocket that has the method of study, and the doctor has to order the analgesic drugs according to the instruction and then covertly write down and record the patient's name in the

pocket of related intervention. The doctor also can not give any information about the the drug to the researcher and the patient. In the case group, 1.5 mg per kg of Ketamine will be diluted in 5 ccs of sterile water and nebulized in 5 minutes, and also 100 ccs of Normal saline serum will infuse intravenously for 15 minutes, and in the in control group 0.1 mg per kg Morphine sulfate will be infused intravenously in 100 ccs of Normal saline and also 5 ccs of sterile water will be nebulized; in order to make the trial double-blinded. After prescribing the analgesic drug, the researcher records the patient's name and Visual Analogue Scale in decided minutes on another sheet and table. After concluding the data collection, the recorded data from the pockets and the researcher's table will be conformed to perform the data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jondishapour Ahvaz university of medical sciences.

Street address

Golestan Hospital, Mofid Ave., Farvardin Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135815751

Approval date

2022-04-18, 1401/01/29

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.016

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain level

Timepoint

Before intervention and in 5, 10, 20, 40, 60 minutes after intervention.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Side effects

Timepoint

60 minutes after receiving an intervention.

Method of measurement

A questionnaire that includes possible side effects after receiving the drugs.

Intervention groups

1

Description

Intervention group: Patients coming to the ER with pain level greater than 7 out of 10 who get treated by 1.5 mg per kg nebulized ketamine.

Category

Treatment - Drugs

2

Description

Control group: Patients coming to the ER with pain level greater than 7 out of 10 who get treated by 0.1 mg per kg intravenous morphine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Hasan Motamed

Street address

Golestan Hospital, Mofid Ave., Farvardin Blvd.

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 61 3311 3816

Fax

+98 61 3320 4516

Email

golestanhospital@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoush Zakerkish

Street address

Golestan Hospital, Mofid Ave., Farvardin Blvd.

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3311 3812

Fax

+98 61 3311 3812

Email

motamed-h@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Sahar Gholamzadeh

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Golestan Hospital, Mofid Ave., Farvardin Blvd.

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 61 3321 4578

Email

sahar.ghz97@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Hasan Motamed

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Golestan Hospital, Mofid Ave., Farvardin Blvd.

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 61 3374 3001

Email

motamed-h@ajums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Sahar Gholamzadeh

Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Golestan Hospital, Mofid Ave., Farvardin Blvd.

City

Ahvaz

Province

Khuzestan

Postal code

6135815751

Phone

+98 61 3321 4578

Email

sahar.ghz97@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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available