

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparison effect of intravenous fentanyl with low dose ketamine on pain relief in methadone user patients with limb fracture

Protocol summary

Study aim

The comparison effect of intravenous fentanyl with low dose ketamine on pain relief in methadone user patients with a limb fracture

Design

A clinical trial without a parallel control group, single-blind, randomized

Settings and conduct

The trial will be conducted on 100 patients at Al-Zahra and Kashani hospitals. In advance, the two drugs will be prepared by an emergency medicine specialist and will be identified in packages coded A and B so that the prescriber, as well as the clinical and baseline patient record holder, is not aware of the type of intervention. Fentanyl and ketamine are used as single doses, with doses of 1-2 µg / kg and 0.3 mg/kg, respectively. Ketamine 0.3 mg/kg will be diluted with 100 ml of normal saline and administered intravenously and slowly for 15 minutes. Demographic data, disease history, vital signs, type of limb fracture, pain score of patients prior to drug administration (at baseline), and at 15, 30 and 60 minutes after drug administration. Possible side effects such as nausea, vomiting, loss of consciousness, hypoxia, hypotension, etc. will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Methadone users with limb fractures; Ages 18 to 65 years; Insensitivity to fentanyl and ketamine; Maxillofacial failure; No pregnancy; Lack of severe head trauma and decreased level of consciousness; No serious trauma to the chest and abdomen; Instability in terms of vital signs; No use of psychotropic drugs; No history of neuropsychiatric disorders; Consent to participate in this stud; Exclusion criteria: Severe hypoxia

Intervention groups

We have two intervention groups. One group received fentanyl and the other group received ketamine.

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N25**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

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st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of intravenous fentanyl with low dose ketamine on pain relief in methadone user patients with limb fracture

Public title

The effect of fentanyl with ketamine on pain relief of methadone users

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Methadone users with limb fractures
Ages 18 to 65 years
Insensitivity to fentanyl and ketamine
Maxillofacial failure
No pregnancy
Lack of severe head trauma and decreased level of consciousness
No serious trauma to the chest and abdomen
Instability in terms of vital signs
No use of psychotropic drugs
No history of neuropsychiatric disorders
Consent to participate in this study.

Exclusion criteria:

Severe hypoxia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The study sample was simple randomly divided into two groups of 20 people, each by selective envelopes. Thus, each envelope containing one of the two A and B labels represented one of the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In advance, the two drugs will be prepared by an emergency medicine specialist and will be identified in packages with codes A and B so that the prescriber is not aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.MUI.MED.REC.1398.043

Health conditions studied

1

Description of health condition studied

limb fracture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score

Timepoint

Before drug administration (at baseline), and at 15, 30 and 60 minutes after drug administration

Method of measurement

Based on Visual analog score from 0 to 10

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: receives Fentanyl ampoules made by Aburaihan pharmaceutical Co. 1-2 mg/kg as single dose intravenously and slowly for 15 minutes.

Category

Treatment - Drugs

2

Description

Second intervention group: receives Ketamine ampoules made by Aburaihan pharmaceutical Co 0.3 mg/kg diluted with 100 ml normal saline and administered as single dose, intravenously and slowly for 15 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Mohsen Farghani

Street address

Sofe Blvd, Isfahan Province, Isfahan

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2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mohsen Farghani

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Kashani Street, Isfahan Province, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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Isfahan University of Medical Sciences, Hezarjarib
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Farajzadegan@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohsen Farghani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Mohsen Farghani

Position

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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

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

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

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Al-Zahra Hospital and Kashani Hospital

What processes are involved for a request to access data/document

After the investigation of researcher request and presentation of required documents will be accessible.

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

Esfahan University of Medical Sciences

Full name of responsible person

Mohsen Farhani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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