

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial to compare the effectiveness of opioid with opioid-ketamine on pain relief in traumatic patients

Protocol summary

Study aim

A clinical trial to compare the effectiveness of opioid with opioid-ketamine on pain relief in traumatic patients

Design

In clinical trial with a control group and double-blind, eighty traumatic patients were chosen allocated using table of random numbers, community-based and pragmatic as parallel groups.

Settings and conduct

Traumatic patients who referred to the emergency department of Besat Hospital, Tehran are chosen as the participants of the study. In this double-blind study, the participants and all of responsible for data collection are unaware of the patient's groups and the type of drug

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 15 and 40 years; having a natural intelligence; no speech problem; according to the diagnosis patients with trauma require the analgesic. Exclusion criteria: Allergy to the drugs studied; having underlying disorder of respiratory, cardiac, neurological; addicted; active psychosis; poisoning clinical.

Intervention groups

The control group is receiving 20 mg opioid with distilled water. The intervention group is receiving 10 mg opioid with 0.1 mg/kg ketamine.

Main outcome variables

Evaluation and comparison of opioid with opioid-ketamine of pain relief based on the visual analog scale, and side-effects of medications (nausea and vomiting, dizziness, dry mouth, euphoria, skin rash in the area of injection, nystagmus, tinnitus, etc) based on questionnaire before, 15 and 30 minutes after intervention between the control and intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181021041399N1**

Registration date: **2018-11-07, 1397/08/16**

Registration timing: **prospective**

Last update: **2018-11-07, 1397/08/16**

Update count: **0**

Registration date

2018-11-07, 1397/08/16

Registrant information

Name

Mehdi Arzani Sams Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3321 6512

Email address

ziahejri@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of opioid with opioid-ketamine on pain relief in traumatic patients

Public title

The effective of opioid-ketamine on pain relief in traumatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 15 and 40 years Having a natural intelligence No speech problem according to the diagnosis patients with trauma require the analgesic

Exclusion criteria:

Allergy to the drugs studied Having underlying disorder of respiratory, cardiac, neurological Addicted Active psychosis Poisoning clinical

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eighty traumatic patients who are referred to the emergency department of Besat Hospital, were chosen allocated using table of random numbers. To this end, a code is allocated to each of the participants to be assigned into one of the two groups of intervention or control

Blinding (investigator's opinion)

Double blinded

Blinding description

Traumatic patients who referred to the emergency department of Besat Hospital, are chosen as the participants of the study. In this double-blind study, the participants and all of responsible for data collection are unaware of the patients groups and the type of drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Republic of Iran Army University of Medical Sciences

Street address

Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh Street, Fatemi Street

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.AJAUMS.REC.1397.011

Health conditions studied

1

Description of health condition studied

Traumatic arthropathy

ICD-10 code

M12.5

ICD-10 code description

Traumatic arthropathy

2

Description of health condition studied

injuries of head

ICD-10 code

S09

ICD-10 code description

Other and unspecified injuries of head

3

Description of health condition studied

Injury of abdominal

ICD-10 code

S35.0

ICD-10 code description

Injury of abdominal aorta

4

Description of health condition studied

Injury of hand region

ICD-10 code

S68.3

ICD-10 code description

Combined traumatic amputation of (part of) finger(s) with other parts of wrist and hand

5

Description of health condition studied

Injury of hand leg

ICD-10 code

T05.4

ICD-10 code description

Traumatic amputation of one foot and other leg [any level, except foot]

Primary outcomes

1

Description

pain relief

Timepoint

before, 15 and 30 minutes

Method of measurement

visual analog scale

Secondary outcomes

1

Description

side-effects of medications (nausea and vomiting, dizziness, dry mouth, euphoria, skin rash in the area of injection, nystagmus, tinnitus, etc)

Timepoint

before, 15 and 30 minutes after intervention

Method of measurement

Designed questionnaire

Intervention groups

1

Description

Control group: who is receiving 20 mg opioid with distilled water

Category

Treatment - Drugs

2

Description

Intervention group: who is receiving 10 mg opioid with 0.1 mg/kg ketamine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Nahaja Hospital

Full name of responsible person

Mehdi Arzani Shams Abadi

Street address

Besat Nahaja Hospital, Basij Highway

City

Tehran

Province

Tehran

Postal code

1735838544

Phone

+98 21 3321 6512

Email

info@website.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mohammad Solemani

Street address

Vice Chancellor for Research, Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh Street, Fatemi Street

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 3321 6512

Email

info@ajaums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Mehdi Arzani Shams Abadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh Street, Fatemi Street

City

Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 3321 6512
Email
me_arzani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mehdi Arzani Shams Abadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh Street, Fatemi Street
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 3321 6512
Fax
Email
me_arzani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mehdi Arzani Shams Abadi
Position
Resident
Latest degree
Medical doctor
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Emergency Medicine

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Islamic Republic of Iran Army University of Medical Sciences, Etemadzadeh Street, Fatemi Street
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Email
me_arzani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results.

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Mehdi Arzani Shams Abadi provides the analysis code to the applicants via email: me_arzani@yahoo.com

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

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments