

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

A clinical trial to compare the effectiveness of ketamine, propofol/ketamin with propofol/fentanil for procedure sedation and analgesia of reduction of shoulder dislocation.

Protocol summary

Study aim

A clinical trial to compare the effectiveness of ketamine, propofol/ketamin with propofol/fentanil for procedure sedation and analgesia of reduction of shoulder dislocation.

Design

150 dislocated shoulder patients who referred to the emergency department of Besat Nahaja Hospital, were chosen randomly and assigned to three intervention groups. A code was allocated to each of the participants.

Settings and conduct

The dislocated shoulder patients who referred to the emergency department of Besat Nahaja 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 15 and 40 years; lack of underlying disease such as blood pressure, diabetic, cardiovascular disease, and etc; having dislocation orthopedic removable at emergency; Normal examination of the neuromuscular system; non allergenic to sedative drugs. Exclusion criteria: Cardiovascular instability; having low saccharification; having multiple trauma; possibility of the abdomen or chest bleeding; having head trauma; decreased alertness.

Intervention groups

The first intervention group are receiving 1-1.5 mg/kg of intravenous ketamine from 30 to 60 seconds. The second intervention group are receiving 1-1.5 mg/kg of intravenous ketamine with 1 mg/kg propofol from 30 to 60 seconds. The third intervention group are receiving 1 mg/kg of intravenous propofol with 50 µg fentanyl from 30 to 60 seconds.

Main outcome variables

Evaluation and comparison of rate of pain base on bispectral index scale (BIS) between three intervention groups before and per minute until the completed reduction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180627040258N1**

Registration date: **2018-07-11, 1397/04/20**

Registration timing: **prospective**

Last update: **2018-07-11, 1397/04/20**

Update count: **0**

Registration date

2018-07-11, 1397/04/20

Registrant information

Name

Masood Shahabian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3321 6512

Email address

m.masaeli@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of ketamine, propofol/ketamin with propofol/fentanil for procedure sedation and analgesia of reduction of shoulder dislocation.

Public title
Procedural sedation and analgesia of reduction of shoulder dislocation.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Aged between 15 and 40 years Lack of underlying disease such as blood pressure, diabetic, cardiovascular disease, and etc Having dislocation orthopedic removable at emergency Normal examination of the neuromuscular system Non allergenic to sedative drug
Exclusion criteria:
 Cardiovascular instability Having low saccharification Having multiple trauma Possibility of the abdomen or chest bleeding Having head trauma Decreased alertness

Age
From **15 years** old to **40 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
A randomized, clinical trial based on random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
The dislocated shoulder patients who referred to the emergency department of Besat Nahaja 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

2018-04-30, 1397/02/10

Ethics committee reference number

IR.AJAUMS.REC.1397.002

Health conditions studied

1

Description of health condition studied

Dislocation of shoulder joint

ICD-10 code

S43.0

ICD-10 code description

Subluxation and dislocation of shoulder joint

Primary outcomes

1

Description

Rate of pain

Timepoint

before and per minute until the completed reduction

Method of measurement

bispectral index scale (BIS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group I: patients are receiving 1-1.5 mg/kg of intravenous ketamine from 30 to 60 seconds.

Category

Treatment - Drugs

2

Description

Intervention group II: patients are revising 1-1.5 mg/kg of intravenous ketamine with 1 mg/kg propofol from 30 to 60 seconds.

Category

Treatment - Drugs

3

Description

Intervention group III: patients are revising 1 mg/kg of intravenous propofol with 50 µg fentanyl from 30 to 60 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Nahaja Hospital

Full name of responsible person

Masood Shahabian

Street address

Besat Nahaja Hospital, Basij Highway

City

Tehran

Province

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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

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info@ajaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

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

Masood Shahabian

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be 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

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

Masood Shahabian provides the analysis code to the
applicants via email: elmpajooh@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