

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the efficacy and side effects of ketamine and Dexmedetomidine in reduction of shoulder dislocation in patients referring to the emergency department of Ahwaz Imam Khomeini and Golestan Hospital in 2017

Protocol summary

Study aim

Comparison of efficacy and complications of ketamine and dexmedetomidine in patients with shoulder dislocation

Design

double-blind clinical trial parallel, patients randomization to the A and B group

Settings and conduct

All patients presenting to ED with shoulder dislocation randomly divided into two groups: Dexmedetomidine nebulize and Ketamine nebulize. The medication is prepared by the fourth person. VAS will be repeated at 0, 10, 20, 30, 60 minutes after intervention.

Participants/Inclusion and exclusion criteria

The criteria for entering the study included all patients with the anterior and posterior shoulder dislocation, aged between 65 and 14 years old, and the exclusion criteria included patients with the fracture in the early graft, widespread injury or open arms, patients with decreased consciousness, patients with Deformity and neurologic lesions are the same organs.

Intervention groups

These individuals will be divided into 2 groups A and B, the first group will receive ketamine nebulizer and the second group will receive doxomentomidine nebulizer.

Main outcome variables

Effect of benefit (less pain and fewer side effects) Ketamine or dexmedetomidine in sedation during reduction of shoulder dislocation leads to improved therapeutic goals and patients' quality of life, a change in policy and health care management, and improved treatment quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180530039917N1**

Registration date: **2018-06-21, 1397/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-21, 1397/03/31**

Update count: **0**

Registration date

2018-06-21, 1397/03/31

Registrant information

Name

Payam Ghoraiian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

ghoraiian.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-23, 1396/04/02

Expected recruitment end date

2018-06-23, 1397/04/02

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

empty

Scientific title

Comparison the efficacy and side effects of ketamine and

Dexmedetomidine in reduction of shoulder dislocation in patients referring to the emergency department of Ahwaz Imam Khomeini and Golestan Hospital in 2017

Public title

Comparison of ketamine and dexmedetomidine in a reduction of shoulder dislocation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inferior and posterior dislocation of shoulder 14 - 65 aged

Exclusion criteria:

Patients with fracture in the primary graph Excessive injury or open dislocation shoulder Patients with reduced consciousness Patients with deformity and neurological lesions in shoulder

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize in two groups with quadri unit Permutational blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients know they are participating in a study that is aimed to compare the efficacy and side effects of ketamine and Dexmedetomidine in the reduction of shoulder dislocation but they are not informed that they receive placebo or Dexmedetomidine. The physician who evaluates the clinical status of patients and the nurse who injects the drug are not aware of the medication that patients receive.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commitee of Jundishapur University of Ahvaz

Street address

Golestan

City

Ahvaz

Province

Khuzestan

Postal code

6435134551

Approval date

2638-09-02, 2017/06/11

Ethics committee reference number

IR.AJUMS.REC.1396.636

Health conditions studied

1

Description of health condition studied

Dislocation of shoulder

ICD-10 code

S43

ICD-10 code description

Dislocation and sprain of joints and ligaments of shoulder girdle

Primary outcomes

1

Description

What is the mean value of VAS score in patients undergoing comorbid reduction of ketamine and doxedetomidine before the intervention at 5, 10, 20, 30 and 60 minutes after receiving the drug?

Timepoint

0,5,10,20 30, 60 minutes after treatment

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The group will receive 1 Mg/Kg Ketamine nebulized

Category

Treatment - Drugs

2

Description

The group will receive 1 micro gram/Kg Dexmedetomidine nebulized

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Payam ghoraian
Street address
Golestan street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Mohammad Badvi
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Ahvaz Jundishapur
University of Medical Sciences, Ahvaz, Iran

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
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Payam Ghoraian
Position
Resident
Latest degree
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Person responsible for updating data

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

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