Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 doxedetomidine 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 neublize 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 doxedetomidine 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 Ghoraian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8670 5503

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ghoraian.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 commite of Jundishapur University of Ahvaz
Street address
Golestan
City
Ahvaz
Province
Khouzestan
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 treatmen
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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56143661

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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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Golestan

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6455134358

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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

Full name of responsible person
Payam Ghoraian

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Person responsible for updating data

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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