# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparing the effect of Dexmedetomidin with Midazolam-Fentanyl in sedation and analgesia in reduction of anterior dislocation of shoulder joint in acute emergency department of Ahvaz Imam Khomeini and Golestan hospitals

## Protocol summary

**Study aim**
comparison the effect of Dexmedetomidin with Midazolam-Fentanyl in sedation and analgesia in reduction of anterior dislocation of shoulder joint

**Design**
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

**Settings and conduct**
Patients will allocate to two equal groups of intervention and control according to table of random numbers. Participants including major eligibility criteria: this study will conduct on 40 patients with anterior dislocation of shoulder joint in Ahvaz Imam Khomeini and Gholestan hospitals.

**Participants/Inclusion and exclusion criteria**
age of 18-50 years; having anterior shoulder dislocation without any other trauma; having pain score of 4-10 based on visual analog score in admission time; having consciousness level in a way that has no appropriate verbal response but normal cardiovascular function.

**Intervention groups**
Patients in group I received intravenous dexmedetomidine 1 microgram/kg loading dose followed by 0.2 µg/kg/h. Patients in group II received intervenus midazolam 0.05 mg/kg in combination with 1 µg /kg midazolam-fentanyl for 10-15 minutes.

**Main outcome variables**
sedation and analgesia

## General information

**Reason for update**

**Acronym**
have no acronym

**IRCT registration information**
IRCT registration number: **IRCT2016021726611N1**
Registration date: **2016-07-11, 1395/04/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-08, 1397/09/17**
Update count: **1**

**Registration date**
2016-07-11, 1395/04/21

**Registrant information**

**Name**
Seyyed Javad Maleki

**Name of organization / entity**
Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**
Vice chancellor for research, Ahwaz Judishapur University of Medical Sciences

**Expected recruitment start date**
2016-02-20, 1394/12/01

**Expected recruitment end date**
2019-01-10, 1397/10/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Comparing the effect of Dexmedetomidin with Midazolam-Fentanyl in sedation and analgesia in reduction of anterior dislocation of shoulder joint in acute emergency department of Ahvaz Imam Khomeini and Golestan hospitals

**Public title**
Comparing the effect of Dexmedetomidin with Midazolam-Fentanyl in sedation and analgesia in reduction of anterior dislocation of shoulder joint

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
age of 18-50 years having anterior shoulder dislocation without any other trauma having pain score of 4-10 based on visual analog score in admission time having consciousness level in a way that has no appropriate verbal response but normal cardiovascular function

**Exclusion criteria:**
decrease of level of consciousness trauma and injury of other limbs pregnancy addiction disability in speaking lack of cooperation allergy to opioids abnormality in vital signs such as systolic blood pressure below 90 mmHg and respiratory rate below 12 beat in minute

**Age**
From **18 years** old to **50 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients will be divided into two equal groups of intervention and control using random numbers.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
After randomization, the intervention was performed in a double-blind manner in which the interventional physician, the patients assessing the pain of the patients, as well as the patients, did not know the group in which they were located. The only second-person study that did not interfere with the collection of data was observing the study, was not blind.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

**Street address**
Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
00986135715794

**Approval date**
2015-09-19, 1394/06/28

**Ethics committee reference number**
IR.AJUMS.REC.1394.361

## Health conditions studied

### 1

**Description of health condition studied**
Dislocation of acromioclavicular joint

**ICD-10 code**
S43.1

**ICD-10 code description**
Dislocation of acromioclavicular joint

## Primary outcomes

### 1

**Description**
Sedation and analgesia

**Timepoint**
10 minutes after intervention

**Method of measurement**
Questionnaire and visual analog sore

## Secondary outcomes

### 1

**Description**
Side effects

**Timepoint**
10-15 minutes after intervention

**Method of measurement**
Researcher-made questionnaire

## Intervention groups

### 1

**Description**
Patients in intervention group will receive Dexmedetomidin via intravenous with dosage of 1 micro-gram per kilogram in 10-15 minutes.
**Category**
Treatment - Drugs

### 2

**Description**
Patients in control group will receive Midazolam with dosage of 0.1 milligram per kilogram via intravenous with Fentanyl in 2-3 micro-grams per kilogram in 10-15 minutes
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ahvaz Imam Khomeini hospital
**Full name of responsible person**
Ali Delirrooy Fard
**Street address**
Emam Khomeini hospital, Ahvaz, Khuzestan
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### 2

**Recruitment center**
**Name of recruitment center**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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**Email**
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**Grant name**
3-9
**Grant code / Reference number**
7
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ahwaz Judishapur 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**
Ahvaz Jundishapur University of Medical Sciences
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Seyyed Javad Maleki
**Position**
Resident of emergency medicine
**Latest degree**
Specialist
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## Person responsible for updating data

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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**
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**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable