

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 613738383

###### Email address

maleki.sj@ajums.ac.ir

##### 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 Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

##### City

Ahvaz

##### Province

Khuzestan

##### 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

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

1579461357

##### Phone

+98 61 3264 2936

##### Email

adelir1982@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Ahvaz Golestan hospital

##### Full name of responsible person

Ali Delirrooy Fard

##### Street address

Golestan hospital, Golestan road, Ahvaz, Khuzestan

##### City

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adelir1982@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz Judishapur University of Medical Sciences

##### Full name of responsible person

Ali Delirrooy Fard

##### Street address

Emergency department of Imam Khomeyni hospital

##### City

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##### Province

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##### Phone

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##### Email

adelir1982@gmail.com

#### Grant name

3-9

#### Grant code / Reference number

7

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

Yes

#### Title of funding source

Ahvaz 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

##### Full name of responsible person

Seyyed Javad Maleki

##### Position

Resident of emergency medicine

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

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Imam Khomeini hospital, Azadegan road, Ahvaz, Khuzestan

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz Jundishapur University of Medical Sciences  
**Full name of responsible person**  
Ali Delirrooy Fard  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### 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**  
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**Other areas of specialty/work**  
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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