

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The comparative study of postoperative shoulder pain under pain anesthesia with sedation for performing the procedure and supracapacular nerve block under ultrasound guide in patients referred to the emergency department

#### Protocol summary

##### Study aim

The comparative study of postoperative shoulder pain under pain anesthesia with sedation for performing the PSA procedure and supracapacular nerve block under ultrasound guide in patients referred to the emergency department

##### Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 50.

##### Settings and conduct

In this research, all patients referred to the Emergency Department of Shohada-e- Haftome tir and Hazrat Rasoul Akram Hospital, who suffered from Shoulder dislocation will be enrolled. Patients will be randomly divided into two groups based on 10 blocks. A total of 100 patients will be examined. Data analyzers will be blind.

##### Participants/Inclusion and exclusion criteria

All patients referred to the Emergency Department of Shohada-e- Haftome tir , Hazrat Rasoul Akram and Firouzgar Hospital, who suffered from Shoulder dislocation will be enrolled. Inclusion criteria: Shoulder dislocation with or without trauma, patients over 18 years old. Exclusion criteria: Patients over 70 years old, The presence of fracture along the dislocation, chronic, kidney and liver disease, systolic pressure less than 90 mmHg, heart rate less than 60 times per minute

##### Intervention groups

In Control group, Ketamine will be given to the patient at a dose of 1-2mg/kg as a titration to provide a suitable sedation. In Intervention group, An ultrasound device is used for the 5 -10 MHz linear probe. The linear probe is placed in parallel with the sphagnum throat, and is injected from the medial to the lateral, about 2-3 mm on the probe medial side, 22 gauge syringe, containing 5 cc of lidocaine in the scapular area.

#### Main outcome variables

Pain relief, Patient Satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151003024317N5**

Registration date: **2019-01-28, 1397/11/08**

Registration timing: **prospective**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

##### Registration date

2019-01-28, 1397/11/08

##### Registrant information

##### Name

Mahdi Rezai

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8868 6772

##### Email address

rezaei.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-09, 1397/11/20

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The comparative study of postoperative shoulder pain under pain anesthesia with sedation for performing the procedure and supracapacular nerve block under ultrasound guide in patients referred to the emergency department

**Public title**  
Shoulder dislocation treatment under the anesthetic with sedation for performing the procedure and supracapacular nerve block

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Shoulder dislocation with or without trauma Patients over 18 years old  
**Exclusion criteria:**  
Patients over 70 years old The presence of fracture along the dislocation Chronic kidney and liver disease Systolic pressure less than 90 mmHg Heart rate less than 60 times per minute

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **100**

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

**Randomization description**  
Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in intervention group and 5 will be in control group. A total of 10 blocks will be considered for sample size.

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

**Blinding description**  
Data will be analyzed by person who is blind to study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2018-12-26, 1397/10/05

#### Ethics committee reference number

IR.IUMS.FMD.REC.1397.127

## Health conditions studied

### 1

#### Description of health condition studied

Shoulder dislocation

#### ICD-10 code

M24.31

#### ICD-10 code description

Pathological dislocation of shoulder, not elsewhere classified

## Primary outcomes

### 1

#### Description

Pain relief

#### Timepoint

After 5, 10 and 15 minutes after using the drug

#### Method of measurement

From 1 to 10 (Based on Visual Analogue Scale).

### 2

#### Description

Patient Satisfaction

#### Timepoint

After the shoulder is laid

#### Method of measurement

From 1 to 5 (Based on numerical scale).

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: An ultrasound device is used for the 5 -10 MHz linear probe. The linear probe is placed in parallel with the sphagnum throat, and is injected from the medial to the lateral, about 2-3 mm on the probe medial side, 22 gauge syringe, containing 5 cc of lidocaine in the scapular area.

### Category

Treatment - Devices

## 2

### Description

Control group: Ketamine will be given to the patient at a dose of 1-2mg/kg as a titration to provide a suitable sedation.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hazrat Rasoul Akram hospital

##### Full name of responsible person

Reza karbor

##### Street address

Emergency department, Hazrate Rasool hospital,  
Niyayesh street, Sattarkhan

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 2190

##### Email

hrmc@iums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shohada-e- Haftome tir Hospital

##### Full name of responsible person

Reza karbor

##### Street address

hospital, Niyayesh street, Sattarkhan

##### City

Tehran

##### Province

Tehran

##### Postal code

1886718136

##### Phone

+98 21 5522 8580

##### Email

web7tir@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Kazem Malakooti

##### Street address

Iran University of Medical Sciences, Hemmat  
Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 8670 2503

##### Email

research@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Reza karbor

##### Position

Emergency Medicine Specialist

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Emergency Departement, Rasool Akram Hospital,  
Niayesh St. Sattarkhan St.

##### City

Tehran

##### Province

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##### Postal code

1344985644

**Phone**

+98 21 6608 0654

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dr\_karbor@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Saieed Abbasi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

hospital, Niyayesh street, Sattarkhan

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**Province**

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**Email**

Saieedabbasi@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza karbor

**Position**

Emergency Medicine Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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**Postal code**

1344985644

**Phone**

+98 21 6608 0654

**Email**

dr\_karbor@yahoo.com

**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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available