

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

Tehran

Postal code

1344985644

Phone

+98 21 6608 0654

Email

dr_karbor@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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

City

Tehran

Province

Tehran

Postal code

1886718136

Phone

+98 21 5522 8580

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

Street address

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

City

Tehran

Province

Tehran

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