

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison between ultrasound-guided interscalene nerve block and procedural sedation with fentanyl and propofol for reduction of anterior shoulder dislocations

Protocol summary

Summary

Objective: To compare two methods of achieving analgesia and muscle relaxation for reduction of anterior shoulder dislocations: procedural sedation with propofol and fentanyl, and ultrasound-guided interscalene nerve block with lidocaine 2%. **Inclusion criteria:** all patients with diagnosis of anterior shoulder dislocation presenting to Bahonar hospital, Kerman, Iran. **Exclusion criteria:** Any contraindications to the drugs assigned for the patient in each group, or any Patient who doesn't accept to enter the study or to undergo the procedure for analgesia which was randomized into; diagnosis of accompanying fracture or neurovascular deficit. **Study population and sample size:** All patients with a diagnosis of anterior shoulder dislocation are enrolled in the study regarding exclusion criteria. For each group (procedural sedation and nerve block), 30 patients will be recruited. **Intervention and outcomes:** Reduction of shoulder dislocations is an emergency procedure and should be done immediately after the diagnosis is confirmed by physical examination and X-rays. Procedural sedation with propofol and fentanyl is one of the most common methods of achieving analgesia and relaxation for reduction of shoulder dislocations. We will perform interscalene nerve block under the guidance of ultrasound by using 30mls of lidocaine 2% and compare the outcome(s) with the propofol and fentanyl group. The primary outcome includes patients' stay time in the emergency department in minute, and secondary outcomes include pain score (by numeric rating scale method) at reduction, patient satisfaction with the procedure, and the number of attempts at reduction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122615941N1**
Registration date: **2015-01-25, 1393/11/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-25, 1393/11/05

Registrant information

Name

Amirhossein Mirafzal

Name of organization / entity

Kerman University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 34 1247 4638

Email address

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Recruitment status

Recruitment complete

Funding source

No funding source available

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between ultrasound-guided interscalene

nerve block and procedural sedation with fentanyl and propofol for reduction of anterior shoulder dislocations

Public title

Interscalene nerve block vs. systemic sedatives for reduction of shoulder dislocations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with diagnosis of anterior shoulder dislocation presenting to Bahonar hospital in Kerman
Exclusion criteria: Any contraindications to the drugs assigned for the patient in each group; Patient doesn't accept to enter the study or to undergo the procedure for analgesia which was randomized into; diagnosis of accompanying fracture in the shoulder joint or neurovascular deficit

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

Afzalipoor paradise, Imam Bouvarde, Kerman, IRAN

City

Kerman

Postal code

Approval date

2013-07-24, 1392/05/02

Ethics committee reference number

10/61/563

Health conditions studied

1

Description of health condition studied

anterior shoulder dislocation

ICD-10 code

M24.3

ICD-10 code description

Pathological dislocation and subluxation of joint, not elsewhere classified

Primary outcomes

1

Description

ED stay time

Timepoint

Discharge time

Method of measurement

Answer sheet- researcher

Secondary outcomes

1

Description

Pain score at reduction

Timepoint

Reduction time

Method of measurement

Researcher- Answer sheet

2

Description

Patient satisfaction

Timepoint

End of Reduction

Method of measurement

Researcher- Answer sheet

3

Description

Total attempts at reduction

Timepoint

End of Reduction

Method of measurement

Researcher- Answer sheet

Intervention groups

1

Description

Intervention: Ultrasound-guided interscalene nerve block with lidocaine 2% 20cc

Category

Treatment - Drugs

2

Description

Control: propofol 1mg/kg IV bolus + fentanyl
2micrograms/kg IV bolus

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Academic Hospital

Full name of responsible person

Amirhossein Mirafzal

Street address

Bagh-e Melli cross st, Shariati St, Kerman, IRAN

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Hayatbakhsh, MD

Street address

Afzaipoor paradise, Imam Khomeini Boulvarde

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Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal MD

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty