Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ranoimized 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 sceinces

Country

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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 ranoimized 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 Boulvarde, 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
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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
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Amirhossein Mirafzal MD
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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