Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of combination of intravenous diazepam and fentanyl with combination of intravenous midazolam and fentanyl in reduction of shoulder joint dislocation in emergency department

Protocol summary

Study aim

1. Determine and compare satisfaction of patients with combination of intravenous diazepam and fentanyl and combination of midazolam and venous fentanyl in onset of shoulder joint 2. Determine and compare the satisfaction of the emergency doctor with the combination of intravenous midazolam and fentanyl and the combination of diazepam and intravenous fentanyl in arthralgic articulation 3. Determine and compare the side effects of drug in diazepam and intravenous fentanyl, and the combination of midazolam and venous fentanyl in the onset of shoulder dislocation

Design

Randomized clinical trial, parallel group with blinded assessment

Settings and conduct

In this study, patients are randomly divided into two groups. In the first group, after receiving the consent of the patient to participate in the study and achieve other entry criteria, a diazepam dose of 0.3 mg / kg will be administered to the patient before reduction and then a standard dose of fentanyl will be used to reduce pain and as soon as the muscles are loosened, the joint will be reduced and the results will be recorded in a special form. In the parallel group, instead of diazepam, midazolam will be given at a dose of 0.03 mg / kg, and the other actions will be similar.

Participants/Inclusion and exclusion criteria

Need for analgesia for joint reduction; no severe underlying illness; age between 18 and 65 years old; aatempt to participate in the study.

Intervention groups

Group one will receive Intravenous diazepam and fentanyl for pre-reduction sedation Group two will receive Intravenous midazolam and fentanyl for pre-reduction sedation

Main outcome variables

Evaluation of pain before, during and after reduction in the patient with Visual Analogue Scale; evaluation of the incidence of adverse drug reactions during and after joint reduction; assess physician's satisfaction during joint reduction with Likert scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170313033051N1**
Registration date: **2019-03-30, 1398/01/10**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-30, 1398/01/10**
Update count: **0**

Registration date

2019-03-30, 1398/01/10

Registrant information

Name

Mohammad Afzalimoghaddam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combination of intravenous diazepam and fentanyl with combination of intravenous midazolam and fentanyl in reduction of shoulder joint dislocation in emergency department

Public title

Effect of intravenous diazepam in reduction shoulder joint dislocation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The need for analgesia for joint reduction No severe underlying diseases Age 18 to 65 years The desire to participate in the study

Exclusion criteria:

Lack of desire to participate in the study Sensitivity to drug used in study Pregnancy Hemodynamic instability Presence of fracture associated with dislocation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are not aware of the type of medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd,.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1962

Health conditions studied

1

Description of health condition studied

Shoulder dislocation

ICD-10 code

S43.0

ICD-10 code description

Subluxation and dislocation of shoulder joint

Primary outcomes

1

Description

Patient satisfaction according to pain scale

Timepoint

Before reduction, during the reduction and after the reduction

Method of measurement

Using Visual Analogue Scale

2

Description

Uncomplicated joint reduction

Timepoint

During the reduction and after the reduction with intervals 15 minutes for 2 hours

Method of measurement

Examination of vital signs and level of consciousness during and after the procedure

3

Description

Physician Satisfaction

Timepoint

After reduction

Method of measurement

sing Likert scale

Secondary outcomes

1

Description
No need for post-reduction care
Timepoint
During and after the reduction for 2 hours and at intervals of 15 minutes
Method of measurement
Using Glasgow Coma Scale and vital sign monitoring with sphygmomanometer and pulse oximeter

Intervention groups

1

Description
Intervention group: Administration of intravenous Diazepam and intravenous Fentanyl. After obtaining the consent of the patient to participate in the study and to place him randomly in this group, Diazepam at a dose of 0.3 mg / kg slowly will be administered intravenously, and as soon as the patient`s muscles will be relaxed, intravenous Fentanyl at a dose of 3 micg / kg will be injected and after about 30 seconds the reduction maneuver has been carried out by traction counter-traction method, and the duration of the reduction and the number of attempts and possible complications are documented.
Category
Treatment - Drugs

2

Description
Control group: After obtaining the consent of the patient to participate in the study and to place him randomly in this group, Midazolamat a dose of 0.1 mg / kg slowly will be administered intravenously, and then intravenous Fentanyl at a dose of 3 micg / kg will be injected and after about 30 seconds the reduction maneuver has been carried out by traction counter-traction method, and the duration of the reduction and the number of attempts and possible complications are documented.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Mohammad Afzalimoghaddam
Street address
Imam Khomeini Hospital, Keshavarz Blvd.
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2

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mohammad Afzalimoghaddam
Street address
Sina Hospital, Imam Khomeini Ave.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
6th floor, Tehran University of Medical Sciences., Qods Ave., Keshavarz Blvd.,
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
msahrai@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Afzalimoghaddam

Position

Associate Profesor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Position

Associate Profesor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main consequence and other consequences can be shared

When the data will become available and for how long

Up to 2 years after completion of the study

To whom data/document is available

Researchers and physicians

Under which criteria data/document could be used

With mention of the source, data can be used in scientific texts

From where data/document is obtainable

Via researcher`s e-mail

What processes are involved for a request to access data/document

After reviewing the application and if possible, it will be answered to the applicant within one month by e-mail.

Comments