

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of intravenous Midazolam, Fentanyl versus intravenous Lidocain, Midazolam and Fentanyl as sedative and analgesic for the reduction of anterior shoulder dislocation in patient presented to Emergency Department

Protocol summary

Summary

The goal of this study is comparison of intravenous Midazolam, Fentanyl versus intravenous Lidocain, Midazolam and Fentanyl as sedative and analgesic for the reduction of anterior shoulder dislocation in patient presented to Emergency Department. This study is double blind randomized clinical trial. 100 patients with anterior shoulder dislocation candidate for close reduction in Emergency Department and do not have any contraindications for administration Lidocain, Midazolam and Fentanyl were randomly divided into two groups. One will be administered intravenous Lidocain, Midazolam and Fentanyl as sedative and analgesic (intervention) and another will be administered intravenous distilled water, Midazolam and Fentanyl (control). The interventional group patients are administered 1mg/kg intravenous lidocain and the same amount of distilled water administered intravenously as a placebo for control group. In both groups midazolam and fentanyl administered intravenously and tit-rated to reach the benchmark 4 from Ramsay score. Then shoulder dislocation will be reduced. Severity of pain was assessed according to Visual Analog Scale before drug administration and also after full consciousness of patient will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101730353N1**

Registration date: **2017-02-12, 1395/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Aida Mohammadian

Name of organization / entity

Imam Hosein hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of intravenous Midazolam, Fentanyl versus intravenous Lidocain, Midazolam and Fentanyl as sedative and analgesic for the reduction of anterior shoulder dislocation in patient presented to Emergency Department

Public title

The role of intravenous Lidocain as sedative and analgesic for the reduction of anterior shoulder dislocation in refereed to Emergency ward of hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with anterior shoulder dislocation
Exclusion criteria: All patients with loss of consciousness; the patient who has shoulder fracture(except hill-sachs lesion); past medical history of shoulder surgery or shoulder fracture; past medical history of epilepsy; cardiac disease or dysrhythmia drug history of using digoxin; all patient with allergy to lidocain midazolam or fentanyl

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Scinces

Street address

Tabnank St, Yaman St, Shahid Chamran highway

City

tehran

Postal code

1985717443

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

ir.sbm.u.sm.rec.1394.22

Health conditions studied

1

Description of health condition studied

anterior shoulder dislocation

ICD-10 code

S43.01

ICD-10 code description

Anterior subluxation and dislocation of humerus

Primary outcomes

1

Description

severity of pain

Timepoint

before sedation and after full conciousnes

Method of measurement

according to VAS (Visual Analog Scale)

Secondary outcomes

1

Description

drug`s side effects: apnea, oxigen saturation decrease less than 90 percent, dysrhythmia, other

Timepoint

after full consciousness

Method of measurement

questionair

Intervention groups

1

Description

In control grup, after pain assesment, patients were gave 5 cc intravenus distilled water. After 5 minute the patients were gave titrate intravenus Midazolam & Fentanyl to reach 4 from ramsay score.

Category

Treatment - Drugs

2

Description

In intervention group, after pain assesment, patients were gave intravenus lidocain 1 mg per kg of patient body weight. After 5 minute the patients were gave titrate intravenus Midazolam & Fentanyl to reach 4 from ramsay score.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Immam Hosein hospital

Full name of responsible person

Ali Arhami Dolatabadi

Street address

Immam Hosein hospital, Shahid Madani St

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Rahmati Roodsari

Street address

Shahid Beheshti University of Medical science,
Tabnak St, Yaman St, Shahid Chamran highway

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Immam Hosein hospital

Full name of responsible person

Aida Mohammadian

Position

emergency medicine resident

Other areas of specialty/work

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Person responsible for updating data

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Position

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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