

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Propofol versus Midazolam for Procedural Sedation of Anterior Shoulder Dislocation in Emergency Department; A Randomized Clinical Trial

Protocol summary

Summary

This study compares the efficacy of two combinations to reduce anterior shoulder dislocation. The subjects in this clinical trial consisted of 48 patients with anterior shoulder dislocation who were randomly assigned to midazolam/fentanyl and propofol/fentanyl groups for PSA. This study was undertaken at the emergency department of Imam Hossein Hospital (Tehran, Iran) between April and August 2011. The two groups were compared to the time interval between injection and induction of sedation (T1), duration of time from sedation to awakening (T2), the duration of time between sedation and full awareness to time, location and individuals (T3), and possible side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501236238N2**

Registration date: **2015-02-23, 1393/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name

Hamid Reza Hatamabadi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 73430

Email address

hhatamabadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Propofol versus Midazolam for Procedural Sedation of Anterior Shoulder Dislocation in Emergency Department; A Randomized Clinical Trial

Public title

Propofol versus Midazolam for Procedural Sedation of Anterior Shoulder Dislocation

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria include anterior dislocation of the shoulder and over 18 years of age. The exclusion criteria include hypersensitivity to midazolam, propofol, or fentanyl; other injury (fracture around shoulder or other limb); intake of food or fluid during last 4 hours; presence of airway difficulty; sensory problems; motor problems, vascular problems, and consumption of alcohol or other recreational drug during past 6 hours.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Daneshjoo Bolvd., Shahid Beheshti
University of Medical Sciences

City

Tehran

Postal code

Approval date

2012-09-20, 1391/06/30

Ethics committee reference number

1393.554

Health conditions studied

1

Description of health condition studied

Dislocation of shoulder joint

ICD-10 code

S40.0

ICD-10 code description

Contusion of shoulder and upper arm

Primary outcomes

1

Description

Success of reduction

Timepoint

after each reducing process

Method of measurement

Physical examination and X-ray

Secondary outcomes

1

Description

Complication

Timepoint

after reduction and each subsequent visit

Method of measurement

History, physical examination and X-ray

Intervention groups

1

Description

Fentanyl injection was initially administered at a dose of 1 µg/kg. Then, a bolus of propofol titrated (slow IV during 30 seconds) until the spontaneous eyelid close.

Category

Treatment - Drugs

2

Description

Fentanyl injection was initially administered at a dose of 1 µg/kg. Then, intravenous midazolam 2mg/kg injected slowly during 30 seconds and titrated to spontaneous eyelid closed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Dr Hamid Reza Hatamabadi

Street address

Emam Hossein Hospital, Shahid Madani St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hamid Reza Hatamabadi

Street address

Emam Hossein Hospital, Shahid Madani St

City

Tehran

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hamid Reza Hatamabadi

Position

Associate professor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Alborz university of medical sciences

Full name of responsible person

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Position

Assistant

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Position

Associate

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Web page address**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