

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The comparison of the success and complications in shoulders reduction with using three drug combination succinylcholine and thiopental "with" propofol and fentanyl "with" midazolam and fentanyl in Imam Hussein hospital of Tehran.

Protocol summary

Summary

This study is a double-blind randomized clinical trial, on 150 patients, with the aim of the comparison of the success and complications in shoulders reduction with using three drug combination succinylcholine and thiopental "with" propofol and fentanyl "with" midazolam and fentanyl in Imam Hussein hospital of Tehran will be done. Inclusion criteria including patients 18 to 65 years old with anterior or posterior shoulder dislocation, Admitted to the emergency, consent to participate in the study and exclusion criteria included physical condition above III based on the ASA, patients with major fracture dislocation, other major injuries, history of drug abuse, patients with poisoning. Patients randomly with using random numbers table will be divided into three groups of 50 Patients. Before the reduction 20 mg succinylcholine and 3.5 mg/kg thiopental in the first group, 3-1 mg/kg propofol and 3-2 mg/kg of fentanyl in the second group and 5-3 mg of midazolam 3-2 mg/kg of fentanyl in the third group will be injected and patients after receiving sedation, emergency assistant will do all of the reduction with Liedelmayer maneuver. The success of the reduction will be monitored with X-ray and evaluated reduction in complications in three groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032323559N10**
Registration date: **2017-04-24, 1396/02/04**
Registration timing: **na**

Last update:

Update count: **0**

Registration date

2017-04-24, 1396/02/04

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 3011

Email address

s.matin@arums.ac.ir

Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the success and complications in shoulders reduction with using three drug combination succinylcholine and thiopental "with" propofol and fentanyl "with" midazolam and fentanyl in Imam Hussein hospital of Tehran.

Public title

Comparison of the three drug combination succinylcholine and thiopental "with" propofol and fentanyl "or" intravenous midazolam and fentanyl "success and complication reduction in shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients 18 to 65 years old with anterior or posterior shoulder dislocation; Admitted to the emergency; consent to participate in the study.
Exclusion criteria: physical condition above III based on the ASA; patients with major fracture dislocation; other major injuries; history of drug abuse; patients with poisoning.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is double-blind. In this study, we have 2 types of envelopes. Envelopes A is containing dexamethasone and ondansetron and Envelopes B which contains dexamethasone and Plazil. Patients by executing and by table of random numbers divided into two A & B groups. According to Patient group, Envelopes For drugs injection will be delivered to anesthesia technician. Anesthesia technician does not know the type of injected drug.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Shahid Erabi St, Yaman St, Shahid Chamran Highway,
Tehran

City

Tehran

Postal code

1985717443

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SBMU.RAM.REC.1394.159

Health conditions studied

1

Description of health condition studied

Reduction of shoulders

ICD-10 code

S43.0

ICD-10 code description

Dislocation of shoulder joint

Primary outcomes

1

Description

Reduction success

Timepoint

Up to 5 minutes after reduction

Method of measurement

Checked by X-ray.

2

Description

Reduction complications

Timepoint

Until clearance

Method of measurement

Through examination of patient

Secondary outcomes

1

Description

Pain score

Timepoint

During reduction

Method of measurement

Based on VAS score

2

Description

Sedation score

Timepoint

During reduction

Method of measurement

Ramsey sedation score

Intervention groups

1

Description

The first group: consists of succinylcholine 20 mg and thiopental with 5.3 mg/kg dose(drugs prescription to titrated and slow injection)

Category

Treatment - Drugs

2

Description

The Second group: consists of propofol with 1-3 mg/kg doses and Fentanyl with 2-3 mg/kg dose(drugs prescription to titrated and slow injection)

Category

Treatment - Drugs

3

Description

The third group: includes a midazolam with 3-5 mg dose and fentanyl with 2-3 mg/kg dose(drugs prescription to titrated and slow injection)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein hospital

Full name of responsible person

Hamid kariman MD

Street address

Emam Hossein Hospital, Madani St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi MD

Street address

College of Medicine, Kodakyari St, Shahid Shahriari Square, Shahid Chamran Highway, Tehran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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

Hamid kariman MD

Position

Associate Professor, Department of Emergency Medicine

Other areas of specialty/work

Street address

Emam Hossein Hospital, Madani St, Tehran

City

Tehran

Postal code

1415813714

Phone

+98 21 7755 8001

Fax

+98 21 7755 8001

Email

h.kariman49@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamid kariman MD

Position

Associate Professor, Department of Emergency Medicine

Other areas of specialty/work

Street address

Emam Hossein Hospital, Madani St, Tehran

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1415813714

Phone

+98 21 7755 8001

Fax

+98 21 7755 8001

Email

h.kariman49@gmail.com

Web page address

+98 21 7755 8001

Person responsible for updating data

Email

h.kariman49@gmail.com

Web page address

Contact

Name of organization / entity

shahid Beheshti University of Medical Sciences

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Street address

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Phone

+98 21 7755 8001

Fax

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