

# 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

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## Person responsible for scientific inquiries

### Contact

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#### Full name of responsible person

Hamid kariman MD

#### Position

Associate Professor, Department of Emergency Medicine

#### Other areas of specialty/work

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**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*