

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of reducing success and complication of shoulder dislocation with “Succinylcholine and Thiopental”, “Propofol and Fentanyl” and “Fentanyl and Midazolam” in Emergency Department

#### Protocol summary

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##### Summary

The aim of this Concurrent/parallel triple blind randomized controlled clinical trial is the Comparison of reducing success and complication of shoulder dislocation with three different palliative and relaxant regimen consist of “Succinylcholine and Thiopental”, “Propofol and Fentanyl” and “Fentanyl and Midazolam” to determine the best mixed regimen with higher success rate and lower complication for our patients in this region. According to block randomization, 150 cases aged between 16 and 65 years with anterior or posterior shoulder dislocation will be allocated into three groups with 50 cases in each.

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of research, Shahid Beheshti University

##### Expected recruitment start date

2010-10-23, 1389/08/01

##### Expected recruitment end date

2011-04-21, 1390/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201009264811N1**

Registration date: **2012-04-28, 1391/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-04-28, 1391/02/09

##### Registrant information

###### Name

Ali Kabir

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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###### Email address

##### Scientific title

Comparison of reducing success and complication of shoulder dislocation with “Succinylcholine and Thiopental”, “Propofol and Fentanyl” and “Fentanyl and Midazolam” in Emergency Department

##### Public title

Clinical trial of different treatments in shoulder dislocation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Cases aged between 16 and 65 with anterior/posterior shoulder dislocation including those with avulsion fracture of the greater tuberosity or of the glenoid labrum who have referred to emergency department and signed a written informed consent.

Exclusion criteria: Patients with physical status higher than II according to American Society of Anesthesiologists (ASA); cases with major fracture-dislocation; cases with other major trauma; history of drug abuse; intoxicated patients.

**Age**

From **16 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple 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**

2012-01-17, 1390/10/27

**Ethics committee reference number**

90-1-134 / 8175

**Health conditions studied****1****Description of health condition studied**

Dislocation of shoulder joint

**ICD-10 code**

S43.0

**ICD-10 code description**

Dislocation of shoulder joint

**2****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**

Protocol A consist of 20 mg Succinylcholine and 100 mg Thiopental

**Category**

Treatment - Drugs

**2****Description**

Protocol B consist of 1-3 mg/Kg Propofol and 2-3 mg/Kg Fentanyl

**Category**

Treatment - Drugs

**3****Description**

Protocol C consist of 2-3 mg/Kg Fentanyl and 3-5 mg Midazolam

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital

**Full name of responsible person**

Dr Afshin Amini

**Street address**

Imam Hossein Hospital, Nezam Abad St.

**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Dr. Afshin Amini

**Street address**  
Imam Hossein Hospital, Nezam Abad St.

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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

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**Position**  
Assistant Professor

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

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MD, MPH

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## Person responsible for updating data

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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*