

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### A comparison of sedation with thiopental-fentanyl versus propofol-fentanyl for anterior shoulder dislocation reduction in Emergency department

#### Protocol summary

##### Study aim

Comparison of the therapeutic effect of thiopental-fentanyl with propofol-fentanyl in providing sedation for reduction of anterior shoulder dislocation

##### Design

This study is a double-blind and two-phase clinical trial. Based on previous studies, 100 people were selected as the sample size.

##### Settings and conduct

This study was performed in the trauma emergency department of Ayatollah Mousavi Hospital as a double-blind trial. In this study, two types of pocket were used. Pocket A contained propofol and fentanyl and envelope B contained thiopental and fentanyl. According to the patient group, the pocket related to that patient was delivered to the nurse for drug injection. The drug was injected in the presence of the researcher by a nurse who injected the type of drug and knew its side effects, but the researcher was not aware of the type of drug.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study, People 18 to 40 years old with anterior shoulder dislocation Exclusion criteria: People with fractures and major dislocations, Other major injuries with hemodynamic disturbances, History of substance abuse, People with allergies to any medications, Pregnancy

##### Intervention groups

In this study, two types of pocket were used. Pocket A contained propofol and fentanyl and envelope B contained thiopental and fentanyl. According to the patient group, the pocket related to that patient was delivered to the nurse for drug injection. The drug was injected in the presence of the researcher by a nurse who injected the type of drug and knew its side effects, but the researcher was not aware of the type of drug. It should be noted that patients did not know the type of sedative injectable.

#### Main outcome variables

Duration of sedation Two sedatives in three stages 1- Start of sedation 2- Between sedation and awakening 3- Between awakening to full consciousness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210626051714N1**  
Registration date: **2021-07-16, 1400/04/25**  
Registration timing: **retrospective**

Last update: **2021-07-16, 1400/04/25**

Update count: **0**

##### Registration date

2021-07-16, 1400/04/25

##### Registrant information

##### Name

Maryam Rouzi Talab

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3313 0000

##### Email address

maryamrouzitalab@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### Actual recruitment start date

2019-12-22, 1398/10/01  
**Actual recruitment end date**  
2021-05-20, 1400/02/30  
**Trial completion date**  
2021-05-20, 1400/02/30

**Scientific title**

A comparison of sedation with thiopental-fentanyl versus propofol-fentanyl for anterior shoulder dislocation reduction in Emergency department

**Public title**

A comparison of sedation with thiopental-fentanyl versus propofol-fentanyl for anterior shoulder dislocation reduction in Emergency department

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Willingness to participate in the study People 18 to 40 years old with anterior shoulder dislocation

**Exclusion criteria:**

Patients with fractures and major dislocations Other major injuries with hemodynamic disturbances History of substance abuse Patients with allergies to any of the drugs Pregnancy

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **100**

Actual sample size reached: **98**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples were selected from 100 patients with anterior shoulder dislocation who referred to the trauma emergency department of Ayatollah Mousavi Hospital, Zanjan University of Medical Sciences. Samples were randomly divided into 50 subjects in the thiopental-fentanyl group and 50 subjects in the propofol-fentanyl group using a random number table. Sampling was continued until the number of samples in each group was completed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study was performed as a double-blind study. In this study, after obtaining informed consent, patients were randomly divided into two groups using a table of random numbers. In this study, two types of pocket were used. pocket A contained propofol and fentanyl and envelope B contained thiopental and fentanyl. According to the patient group, the pocket related to that patient was delivered to the nurse for drug injection. The drug

was injected in the presence of the researcher by a nurse who injected the type of drug and knew its side effects, but the researcher was not aware of the type of drug. It should be noted that patients did not know the type of sedative injectable.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Deputy of Research and Technology of Zanjan University of Medical Sciences

**Street address**

Deputy of Research and Technology, third floor, Second building, Central Headquarters of Zanjan University of Medical Sciences, The beginning of Jomhuri Eslami Boulevard, Azadi Blv, Zanjan, Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Approval date**

2019-08-27, 1398/06/05

**Ethics committee reference number**

IR.ZUMS.REC.1398.220

**Health conditions studied**

**1**

**Description of health condition studied**

Anterior Shoulder Dislocations

**ICD-10 code**

S43.016A

**ICD-10 code description**

Anterior dislocation of unspecified humerus, initial encounter

**Primary outcomes**

**1**

**Description**

Duration of sedation in three stages 1- Start of sedation 2- Between sedation and awakening 3- Between awakening to full consciousness

**Timepoint**

1- Start of sedation 2- Between sedation and awakening 3- Between awakening to full consciousness

**Method of measurement**

Using a stopwatch

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In group A patients, propofol - 0.5 mg / kg fentanyl  $\mu\text{g}/\text{kg}$  was used as intervention group A.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: In group B, thiopental was used titrated to 1 mg / kg - fentanyl 1  $\mu\text{g}/\text{kg}$ .

**Category**

Treatment - Drugs

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

Ayatollah Mousavi Hospital

**Full name of responsible person**

Dr. Nayereh Garjani

**Street address**

Ayatollah Mousavi Hospital, Gavazang Street, Soboti Blv, Zanzan, Iran

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Zanzan

**Province**

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Mousavihospital@zums.ac.ir

**Web page address**

[http://zums.ac.ir/index.php?slc\\_lang=fa&sid=19](http://zums.ac.ir/index.php?slc_lang=fa&sid=19)

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zanzan University of Medical Sciences

**Full name of responsible person**

Dr. Mazyar Payda

**Street address**

Vice chancellor for research, Zanzan University of Medical Sciences, Azadi Blvd. Zanzan

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[http://zums.ac.ir/index.php?slc\\_lang=fa&sid=3](http://zums.ac.ir/index.php?slc_lang=fa&sid=3)

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanzan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Zanzan University of Medical Sciences

**Full name of responsible person**

Dr. Nayereh Garjani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Nayereh Garjani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Maryam Rouzitalab

**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After completing the study, there is a plan to share non-identifiable individual data of the participants, the study protocol, the statistical analysis of the data, the informed consent form patents, clinical reports, analysis codes, and data coding systems (Dictionary).

**When the data will become available and for how long**

The start of the access period to the data of this study will be from Early 2022 and approximately 6 months after the publication of the results.

**To whom data/document is available**

The data from this study will be available to all people who can play a role in caring for Anterior Shoulder Dislocations patients, such as families, and healthcare workers.

**Under which criteria data/document could be used**

The researcher tend to use data to improve patients, especially Anterior Shoulder Dislocations patients.

**From where data/document is obtainable**

To receive information anyone can be use the following email:ngarjani@zums.ac.ir

**What processes are involved for a request to access data/document**

The data will be sended to the applicants after her introduction and the reason for the need for data.

**Comments**