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)

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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 µg/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 µg/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
Ayatolllah Mousavi Hospital, Gavazang Street, Soboti Blv, Zanjan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Mazyar Payda
Street address
Vice chancellor for research, Zanjan University of Medical Sciences, Azadi Blvd. Zanjan
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Email
Research@zums.ac.ir
Web page address
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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Nayereh Garjani
Position
Assistant professor
Latest degree
Specialist
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Emergency Medicine
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Person responsible for updating data

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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