Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

comparison of effectiveness of thiopental versus midazolam in patients with shoulder dislocation who come to emergency department of Shariati and Imam Khomeini Hospitals

Protocol summary

Summary

Aims: To comparison effectiveness of midazolam versus thiopantal in patients with shoulder dislocation who come to emergency departments of Shariati and Imam Khomeini Hospitals. Inclusion criteria: All patients who is suffering from shoulder dislocation will enrolled to the study.Major exclusion criteria: unwilling to study participation, drugs sensitivity, fracture dislocation. Study community: All patients come to emergency departments of Shariati and Imam Khomeini Hospitals with shoulder dislocation.Sample size: 60 patients. Intervention: It is a randomized double blind and parallel clinical trial and patients randomly assign as interventions or controls. In interventions patients receive thiopantal (1-2 mg/kg) I.V. with fentanyl (1-2 microgr/kg) I.V. for sedation and controls receive midazolam (0.05-0.1 mg/kg) I.V. with fentanyl (1-2 microgr/kg) I.V. for sedation. Duration of intervention: 2014.08.22 till 2014.12.22. Outcomes: time of starting loss of conciseness and and time of arousal from sedation. Muscle relaxation, patients and physician satisfaction, pain before and after reduction and number of physician effort for reduction and also complications will evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408068872N5**
Registration date: **2014-08-23, 1393/06/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-23, 1393/06/01

Registrant information

Name
Morteza Saeedi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8490 2719
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m_saeedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of effectiveness of thiopental versus midazolam in patients with shoulder dislocation who come to emergency department of Shariati and Imam Khomeini Hospitals

Public title

comparison of effectiveness of thiopental versus midazolam in patients with shoulder dislocation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias: All patients come come to Shariati and

Imam Khomeini Hospitals with shoulder dislocatin during study period will enrolled to the study. Exclustion criterias: Severe nourovascular damages; coming after 24 hours; fracture dislocation; multiple trauma patient; unwilling to study participation; decreased level of conciousness; unstable vital signs; drugs sensitivity; ilicit drug abusers; age < 18; pregnant women; hepato renal disorders.

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Gods Street, Keshavarz Ave.
City
Tehran
Postal code
Approval date
2014-07-08, 1393/04/17
Ethics committee reference number
93/d/130/858

Health conditions studied

1

Description of health condition studied
shoulder dislocation
ICD-10 code
S43.0
ICD-10 code description
Dislocation of shoulder joint

Primary outcomes

1

Description
number of effort for reduction
Timepoint
after termination of reduction
Method of measurement
question from physician

2

Description
muscle relaxation
Timepoint
after termination of reduction
Method of measurement
qualitave questionnaire

3

Description
pain evaluation
Timepoint
before and just after reduction
Method of measurement
Neumeric Rating Scale

4

Description
loss of conciousness time
Timepoint
one time after loss of responsiveness
Method of measurement
second, cornometer

5

Description
time of arousal
Timepoint
time of full responsiveness
Method of measurement
second, cornometer

Secondary outcomes

1

Description
Patient satisfaction
Timepoint
After termination of Procedure
Method of measurement
Qualitative questionnare

2

Description
physician satisfaction
Timepoint

After termination of Procedure

Method of measurement

Qualitative questionnare

3

Description

complications

Timepoint

After termination of procidure

Method of measurement

questionnare(apnea, long decreased level of contiousness, nausea and vomiting, chest wall rigidity)

Intervention groups

1

Description

In control group, patients receive midazolam (0.05-0.1 mg/kg) I.V. with fentanyl (1-2 microgr/kg) I.V. for sedation.

Category

Treatment - Drugs

2

Description

In intervention group, patients receive thiopantal (1-2 mg/kg) I.V. with fentanyl (1-2 microgr/kg) I.V. for sedation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Morteza Saeedi

Street address

North Amirabad street

City

Tehran

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Rezvan Hemati

Street address

Chamran highway, West Bagherkhan street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh Basti

Street address

No. 1, North door of Tehran university, Poursina street, Enghelab street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Morteza Saeedi

Position

assistant professor/ Emergeny Medicine specialist

Other areas of specialty/work

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Other areas of specialty/work
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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