

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intravenous sedation with midazolam/fentanyl and thiopental/ fentanyl for orthopedic procedures of upper extremities

Protocol summary

Summary

To compare the effects of intravenous sedation with midazolam/fentanyl and thiopental/ fentanyl for orthopedic procedures of upper extremities. Population of this study are patients with age range between 15 and 60 years old from both sex who have dislocation of shoulder joint or fracture of radius. For this study according to sample size measurement, we need 92 patients. Multiple trauma or fractures, history of allergic reaction to study drugs will be excluded from this study. We will perform a randomized clinical trial in Hazrat Rasoul Akram and Sina hospitals. All the patients who fulfill the inclusion criteria would be randomly allocated to one of the study groups. In each group, under cardiac monitoring, pulse oximetry and non invasive blood pressure control drugs with recommended doses will be used. Time of drug injection, beginning and duration of sedation, recovery time, satisfaction of the physician who perform the procedure and side effects will be recorded. SPSS software will be used for analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110307751N2**

Registration date: **2012-04-17, 1391/01/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-17, 1391/01/29

Registrant information

Name

Davood Farsi

Name of organization / entity

TUMS

Country

Iran (Islamic Republic of)

Phone

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Email address

dfarsi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous sedation with midazolam/fentanyl and thiopental/ fentanyl for orthopedic procedures of upper extremities

Public title

Comparison of midazolam/fentanyl and thiopental/ fentanyl for fracture and dislocation reduction of upper arm

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Orthopedic injuries of upper extremities in 15-60 years old patients with American Society of Anesthesiologist (ASA) Classification Score 1& 2
Exclusion criteria: Pregnancy, multiple trauma or fractures, history of allergic reaction to study drugs, or asthma, heart failure, porphyria, mental disorders or

psychosis

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **92**

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
Tehran university of medical sciences

City
Tehran

Postal code
1445613131

Approval date
2012-02-26, 1390/12/07

Ethics committee reference number
2343

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
Fracture of lower end of both ulna and radius

ICD-10 code
S52/6

ICD-10 code description

Fracture of lower end of both ulna and radius

Primary outcomes

1

Description
pain score

Timepoint
before procuder,on time procuder,5 minut after
procuder,15 minut after procuder

Method of measurement
numeric rating scale

Secondary outcomes

1

Description
BP

Timepoint
Before procedure,on time procedure,end of procedure,5
and 15 minute of procedure

Method of measurement
Osillometry

2

Description
SaO2

Timepoint
Before procedure,on time procedure,end of procedure,5
and 15 minute of procedure

Method of measurement
Puls oxymetry

3

Description
HR

Timepoint
Before procedure,on time procedure,end of procedure,5
and 15 minute of procedure

Method of measurement
Cardiac monitoring

4

Description
Pain

Timepoint
Before procedure,on time procedure,end of procedure,5
and 15 minute of procedure

Method of measurement
Numeric rating scale

Intervention groups

1

Description

In control group thiopental (2 mg/kg) and fentanyl (1.5 mg/kg) is used and compared with midazolam (0.1-0.5 mg/kg) and fentanyl (1.5 mg/kg). In case of needing additional doses, half of the first dose is used.

Category

Treatment - Drugs

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

Sina hospital and Hazrate Rasol Hospital

Full name of responsible person

Dr Davood Farsi

Street address

Hazrate Rasol Hospital, Niayesh Avenue

City

Tehran

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Farsi Davood

Position

Assistant Profesor

Other areas of specialty/work**Street address**

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran Universty of Medical Sciences

Full name of responsible person

Dr Akhondzadeh Shahin

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Tehran Universty of Medical Sciences, Tehran, Iran

City

Tehran

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

Yes

Title of funding source

Tehran Universty 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****Person responsible for scientific inquiries****Contact****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Dokhtvasi Ghasem

Position

Resident of Emergency Medicine

Other areas of specialty/work**Street address**

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Web page address**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