Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of evaluating effect of intravenous midazolam on duration of spinal anesthesia in comparison to control group

Protocol summary

Summary

This study is going to evaluate the effect of intravenous midazolam on duration of sensory and motor block in spinal anesthesia. This study will be a double blind clinical trial on 36 candidates of elective lower abdomen and lower limb surgeries under spinal anesthesia in Alzahra Medical Center (Isfahan, Iran). Patients who meet the inclusion criteria such as age between (20-60) years old, American Society of Anesthesiologists classification (ASA) of I and II, no contraindication for the consumption of midazolam or benzodiazepine and no history of alcohol or other substance abuse will be enrolled in this study. Patients will be selected by simple sampling and randomized into two groups of 18 patients each by randomization software. All patients will receive 10 cc/kg Ringer's lactate serum before spinal anesthesia. Spinal anesthesia will be performed by 2 ml of lidocaine 5% in sitting position at L3-L4 or L4-L5 intersegments. The subjects in the first group will receive 0.03 mg/kg midazolam and 1 µg/kg fentanyl intravenously with the time interval of five minutes. Patients in the second group (control group) will receive normal saline (2cc) plus 1 µg/kg fentanyl intravenously with the same time interval. An anesthesiologist, who will not be involved in the study, prepares the study solutions. Therefore, patients and investigators will be blinded to the patient group assignment. The highest dermatome level of sensory blockade, time to achieve maximum motor and sensory block level, duration of sensory and motor block and any side effect (regarding hypotension, nausea, vomiting) will be measured by an investigator. Moreover, heart rate, systolic and diastolic blood pressures, arterial oxygen saturation and sedation score will be recorded at five minutes before surgery and later every five minutes during the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090716415N5**
Registration date: **2014-09-29, 1393/07/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Isfahan University of medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluating effect of intravenous

midazolam on duration of spinal anesthesia in comparison to control group

Public title
Evaluating effect of intravenous midazolam on duration of spinal anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
20 to 60 years old; class American Society of Anesthesiologists (ASA) I or II; no contraindication for midazolam; no benzodiazepine medication before surgery; no history of alcohol or other substance abuse
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
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 Isfahan University of Medical Sciences
Street address
Deputy of Research and Technology, Isfahan University of Medical Sciences, Hezarjarib Boulevard, Isfahan, Iran
City
Isfahan
Postal code
Approval date
2014-05-17, 1393/02/27
Ethics committee reference number
2662/8/د

Health conditions studied

1

Description of health condition studied
Spinal Anesthesia
ICD-10 code
E938.7
ICD-10 code description
Spinal anesthetics causing adverse effects in therapeutic use

Primary outcomes

1

Description
Duration of sensory and motor block
Timepoint
Every 2-5 minutes
Method of measurement
Pinprick testing

Secondary outcomes

1

Description
Sedation Score
Timepoint
Every 5 minutes
Method of measurement
Ramsy Sedation Score

Intervention groups

1

Description
Intravenous Midazolam injection
Category
Treatment - Drugs

2

Description
Intravenous normal saline (placebo)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Medical Center
Full name of responsible person
Golparvar M. MD
Street address
Department of Anesthesia, Alzahra Medical center, Sofeh boulevard, Isfahan, Iran
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research and technology of Isfahan University of Medical Sciences

Full name of responsible person
Dr Alimohammad Sabzeghabaei

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Research manager office, Deputy of research and technology, Isfahan University of Medical Sciences, Hezarjarib Boulevard, Isfahan, Iran

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Deputy of Research and technology of Isfahan 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
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Position
Associated professor in Medical School of Isfahan University of Medical Sciences

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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