

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of sedation by Propofol and Midazolam on cognitive performance in patients older than 65 years candidate for Hip surgery undergoing spinal anesthesia: double blind clinical trial

Protocol summary

Study aim

Comparison of the effect of sedation by Propofol and Midazolam on cognitive performance in patients older than 65 years candidate for hip surgery undergoing spinal anesthesia: double blind clinical trial

Design

136 Patients over 65 years old candidate for hip surgery undergoing spinal anesthesia will be in double blind randomized clinical trial. in one of the two intravenous administration of 0.2 mg/kg Propofol and 0.02 mg/kg Midazolam.

Settings and conduct

In this study, patients older than 65 years candidate for hip surgery undergoing spinal anesthesia who will be referred to the Besat Hospital of Hamadan during the study period, will be randomly assigned to randomized allocation blocks by random sampling.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients older than 65 years; Patients with ASA class 1 and 2; Patients candidate for Hip surgery undergoing spinal anesthesia. Exclusion Criteria: Failure to spinal anesthesia and general anesthesia; Patients with history of alcohol and drug use, sedation and anticonvulsants; History sensitivity to anesthetic drugs; History of cognitive impairment; Spinal anesthesia contraindications

Intervention groups

Intervention group 1: The amount of 0.2 mg/kg Propofol intravenously after spinal anesthesia by an anesthesiologist injected intravenously. 2 intervention groups: the amount of 0.02 mg/kg Midazolam after spinal anesthesia by an anesthesiologist injected intravenously.

Main outcome variables

The percentage of people who have Mini Mental State Examination scores less than 20 after spinal anesthesia and taking Propofol or Midazolam. Systolic and Diastolic Blood Pressure, Nausea & vomiting, Heart Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N19**

Registration date: **2019-07-01, 1398/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-01, 1398/04/10**

Update count: **0**

Registration date

2019-07-01, 1398/04/10

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-21, 1397/12/02

Expected recruitment end date

2021-02-20, 1399/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the effect of sedation by Propofol and Midazolam on cognitive performance in patients older than 65 years candidate for Hip surgery undergoing spinal anesthesia: double blind clinical trial
Public title	Effect of sedation by propofol and midazolam on cognitive performance
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Patients older than 65 years Patients with ASA class 1 and 2 Patients candidate for hip surgery undergoing spinal anesthesia
Exclusion criteria:	Failure to spinal anesthesia and general anesthesia Patients with history of alcohol and drug use, sedation and anticonvulsants History sensitivity to anesthetic drugs History of cognitive impairment Spinal anesthesia contraindications
Age	From 65 years old
Gender	Both
Phase	2-3
Groups that have been masked	• Participant • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 136
Randomization (investigator's opinion)	Randomized
Randomization description	We write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table. With each of the qualified patients, one of the papers is taken out randomly and, According to the text, the patient is given one of two groups: A (Propofol) and B (Midazolam). Then, for four subsequent patients, the paper is returned to the bag again, and this process is repeated until the end of the sample volume.
Blinding (investigator's opinion)	Double blinded
Blinding description	In both groups A and B, medications after spinal anesthesia one of two drugs (Propofol or Midazolam) will be prescribed. In order to prevent the medication being detectable for patients and investigators, they are prepared and injected into syringes of the same size and shape and on the adhesives A and B by the anesthetist. Since drugs are prescribed by an anesthetist, the clinician will not be aware of the type of prescribed medication that will measure and record the outcome of the study.

Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Hamadan University of Medical Sciences
Street address	Mahdieh Street
City	Hamadan
Province	Hamadan
Postal code	6517838678
Approval date	2019-03-09, 1397/12/18
Ethics committee reference number	IR.UMSHA.REC.1397.966
Health conditions studied	
<u>1</u>	
Description of health condition studied	Cognitive disorders following hip surgery under spinal anesthesia
ICD-10 code	G31.1
ICD-10 code description	Senile degeneration of brain, not elsewhere classified
Primary outcomes	
<u>1</u>	
Description	The percentage of people who have Mini Mental State Examination scores less than 20 after spinal anesthesia and taking Propofol or Midazolam.
Timepoint	The day before surgery and before discharging from the hospital
Method of measurement	Using Mini Mental State Examination questionnaire
Secondary outcomes	

1

Description

Nausea & vomiting

Timepoint

After surgery

Method of measurement

Observation

2

Description

Systolic and Diastolic Blood Pressure

Timepoint

Every three minutes to 20 minutes and then every 10 minutes until the end of the surgery

Method of measurement

Non-invasive automatic barometric device

3

Description

Heart Rate

Timepoint

Every three minutes to 20 minutes and then every 10 minutes until the end of the surgery

Method of measurement

Using a pulse oximeter

Intervention groups

1

Description

First Intervention group : The amount of 0.2 mg/kg Propofol 1%(10mg/ml and made by B.BRAUN company in Germany), is injected intravenously after spinal anesthesia by anesthesiologist.

Category

Treatment - Drugs

2

Description

Second Intervention group: The amount of 0.02 mg/kg Midazolam(1mg/ml and made by Caspian pharmaceutical company in Iran), is injected intravenously after spinal anesthesia by anesthesiologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences

Street address

Besat Hospital in Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available