

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of propofol and midazolam sedation dose on patients headache after spinal anesthesia

Protocol summary

Summary

The aim of this study is to compare the effect of propofol with midazolam on headache after spinal puncture . Inclusion criteria:Age 20 to 80 years old : sign the written consent. Exclusion Criteria: the patients aren't included in the first and second class (based on the American Society of Anesthesia classification); coagulopathy disorders; hemodynamic disorders.This study is a double blind clinical trial.80 patients whom refer to the operating room of 15 khordadad hospital of Gonabad for elective surgery in the sitting position are injected with the 25 quinke spinal needle in the space between L4 and L5 through marcaine drug. In this study, half of the patients take 30 mic/kg/min propofol with /02 mg/kg midazolamand for sedation and The patients were examined for headache (none, mild, moderate, or severe) each 6 h to 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120712312N3**

Registration date: **2016-01-21, 1394/11/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-21, 1394/11/01

Registrant information

Name

Mohammadtaghi Khodadadi

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology Gonabad University of Medical Sciences

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of propofol and midazolam sedation dose on patients headache after spinal anesthesia

Public title

The Effect of propofol and midazolam on patients headache after spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who have been admitted as an elective surgery between 20 and 80years old: sign the written consent. Exclusion Criteria: the patients aren't included in the first and second class (based on the American Society of Anesthesia classification); not to sign the written consent; to have an underlying disease; to report any acute or chronic headache before spinal puncture; to take pain medication in the last two days; coagulopathy disorders; hemodynamic disorders; abscesses and local infection of the soft tissue or skin in

the injection site; severe restlessness; brain lesion; severe mental disorders and addictions.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Ethics comity of vice research of Gonabad University of Medical Sciences

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Pardice ,Gonabad University of Medical Sciences

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Postal code

9691793718

Approval date

2015-12-23, 1394/10/02

Ethics committee reference number

IR.GMU.REC.1394.62

Health conditions studied**1****Description of health condition studied**

post spinal headache

ICD-10 code

G97.1

ICD-10 code description

Other reaction to spinal and lumbar puncture

Primary outcomes**1****Description**

Headache

Timepoint

q 6 hr for 24 hours

Method of measurement

vas and check list

Secondary outcomes

empty

Intervention groups**1****Description**

Prescription of intravenous propofol 30 ug/kg/min for sedation post spinal

Category

Treatment - Drugs

2**Description**

Prescription of intravenous midazolam /02mg/kg for sedation post spinal

Category

Treatment - Drugs

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

15 khordadad bidokht hospital

Full name of responsible person

Dr Mohammad Taghi Khodadadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research and technology of Gonabad University of Medical Sciences

Full name of responsible person

Dr Alireza Mohammadzade

Street address

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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

Deputy of Research and technology of Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist

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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*