Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
Phone
+98 51 5723 1114
Email address
dr_khodadadi_m@yahoo.com

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

Street address
Pardice ،Gonabad University of Medical Sciences

City
Gonabad،

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 houre

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 haspital

Full name of responsible person
Dr Mohammad Taghi Khodadadi

Street address
Gonabad Medical University of Sciences

City
Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of Research and technolgy of Gonabad University of Medical Sciences

Full name of responsible person
Dr Alireza Mohammadzade

Street address
Gonabad

City
Gonabad

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 technolgy 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
Dr Mohammad Taghi Khodadadi
Position
Anesthesiologist
Other areas of specialty/work
Street address
15 Khordad bidokht haspital ،Gonabad
City
Gonabad
Postal code
9691793718
Phone
+98 51 5723 1114
Fax
+98 57231114
Email
dr_khodadadi_m@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr Mohammad Taghi Khodadadi
Position
Anesthesiologist
Other areas of specialty/work
Street address
bidokht haspital،Gonabad
City
Gonabad
Postal code
9691793718
Phone
+98 51 5723 1114
Fax
+98 51 5723 1114
Email
dr_khodadadi_m@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical sciences
Full name of responsible person
Dr Mohammad Taghi Khodadadi
Position
Anesthesiologist
Other areas of specialty/work
Street address
15 Khordada bidokht haspital،Gonabad
City
Gonabad
Postal code
9691793718
Phone
+98 51 5723 1114
Fax
+98 57231114
Email
dr_khodadadi_m@yahoo.com
Web page address
mahdikh55@yahoo.com

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