Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of general anesthesia and regional anesthesia in clinical outcome of lumbar spine surgery

Protocol summary

Study aim
Comparison of the effects of general anesthesia and regional anesthesia in the clinical outcome of spinal surgery

Design
A randomized clinical trial with parallel group design on 100 patients.

Settings and conduct
Patients admitted to the neurosurgery ward of Imam Hossein Hospital in Tehran admitted with a diagnosis of discopathy and no pedicle screw indication Informed consent for both methods includes general anesthesia or regional anesthesia.

Participants/Inclusion and exclusion criteria
All patients with spinal discopathy who need surgery for the first time and have no history of hepatic, renal, and pulmonary failure, and the presence of any coagulopathy

Intervention groups
50% of patients take general anesthesia and 50% take regional anesthesia

Main outcome variables
Oswestry disability index; bleeding volume during and after surgery; surgery duration; anesthesia duration; acetaminophen dose usage

General information

Reason for update
To clarify to more extent, literary corrections were made.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210722051955N1**
Registration date: **2021-08-07, 1400/05/16**
Registration timing: **prospective**

Last update: **2023-05-29, 1402/03/08**
Update count: **1**

Registration date
2021-08-07, 1400/05/16

Registrant information

Name
Ahmadreza Vahdati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2613 4479

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of general anesthesia and regional anesthesia in clinical outcome of lumbar spine surgery

Public title
A comparative study of general anesthesia vs regional anesthesia in spinal surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with discopathy who need surgery Signing a written consent to enter the study Spinal surgery for the first time

Exclusion criteria:
Pedicle screw indication Renal, hepatic or pulmonary failure Coagolopathy Contraindication for regional anesthesia

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
All patients who enrolled in the study will given a random number and through a randomized table will be divided into 2 groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
SBMU. Daneshjoo Blvd., Darakeh

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2021-02-16, 1399/11/28

Ethics committee reference number
IR.SBMU.MSP.REC.1399.716

Health conditions studied

1

Description of health condition studied
Lumbar discopathy

ICD-10 code
M51.1

ICD-10 code description
Thoracic, thoracolumbar and lumbosacral intervertebral disc disorder with radiculopathy

Primary outcomes

1

Description
Operation duration

Timepoint
Start and end point of the surgery

Method of measurement
Time based on minutes

Secondary outcomes

1

Description
Blood loss

Timepoint
Before surgery and the point of discharge

Method of measurement
Hemoglobin and volume of drainage

2

Description
Pain

Timepoint
After surgery

Method of measurement
Used paracetamol in gram

3

Description
Vital signs

Timepoint
Before procedure, Prone position, Supine position

Method of measurement
Heart Rate , Blood Pressure

4

Description
Nausea/Vomiting

Timepoint
After surgery

Method of measurement
Used antiemetic and subjective patient complaint

Intervention groups

1

Description
Intervention group: Regional anesthesia with epidural injection of Pethidine 1mg/kg (Aburaihan co) and intravenous injection of Dexmedetomidine 0.2µg/kg (Exir

co)
Category
Treatment - Surgery

2

Description
Control group: In General anesthesia group . Induction with Propofol 2mg/kg and Fentanyl 4mg/kg (Caspian co) and Maintenance with Isoflurane (Baxter co).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Ahmadreza Vahdati
Street address
Madani st. Nezam Abad. Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ali Ziae
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ahmadreza Vahdati
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information is publishable except names of patients.

When the data will become available and for how long

1 year after publish

To whom data/document is available

Everyone

Under which criteria data/document could be used

Unlimited

From where data/document is obtainable

Personal email

What processes are involved for a request to access data/document

1 week after email reception

Comments