Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of General Anesthesia and Combined General Epidural Anesthesia regarding bleeding and post-operative pain after lumbar discectomy surgeries

Protocol summary

Summary

The aim of this single blind randomized clinical trial is comparing general anesthesia with general anesthesia combined with epidural anesthesia regarding bleeding and pain after the operation. In this study, 60 patients who are eligible for study inclusion and exclusion criteria allocate in one of the intervention or control groups. Intervention group patients in the supine position will be anesthetized by epidural anesthesia then placed in a supine position and anesthetized genarally. In the control group patients will only be anesthetized genarally in the same way that the Intervention group will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109173773N5**
Registration date: **2012-01-05, 1390/10/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-01-05, 1390/10/15

Registrant information

Name

Farsad Imani

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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imanifar@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of General Anesthesia and Combined General Epidural Anesthesia regarding bleeding and post-operative pain after lumbar discectomy surgeries

Public title

Comparison of General Anesthesia and Combined General Epidural Anesthesia regarding bleeding and post-operative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing discectomy operation for disc herniation at 1-2 levels. Exclusion criteria: A.S.A class more than 3, Multilevel spinal stenosis (more 2 level), coagulopathy, lumbar localized infection, lumbar region abnormalities, and patients who have contraindications for regional anesthesia.

Age

No age limit

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences-Research administration
Street address
Keshavarz Bv. Ghods st. Cross
City
Tehran
Postal code
Approval date
2011-08-14, 1390/05/23
Ethics committee reference number
807/130/90/د

Health conditions studied

1

Description of health condition studied
Lumbar post-operative pain
ICD-10 code
T02.7
ICD-10 code description
Fractures involving thorax with lower back and pelvis with limbs

2

Description of health condition studied
bleeding during lumbar operation
ICD-10 code
I95.9
ICD-10 code description
Hypotension, unspecified

Primary outcomes

1

Description
Bleeding
Timepoint
during operation
Method of measurement
milliliter

2

Description
Pain
Timepoint
At 5, 10, 15, 20 minutes at recovery & 4, 10, 24 hour after operation at ward
Method of measurement
Visual Analogue Scale = VAS

Secondary outcomes

1

Description
Blood Hb
Timepoint
afetr operation
Method of measurement
gr%

2

Description
Mean Blood Pressure
Timepoint
During operation
Method of measurement
Monitoring Devices

3

Description
Heart Rate
Timepoint
During operation
Method of measurement
Monitoring devices

4

Description
Morphine
Timepoint
During 1 day after operation
Method of measurement
Milligram

Intervention groups

1

Description
Intervention group first receive epidural anesthesia in sitting position (by number 9 catheter and 10 cc Lidocaine 1% +10 cc Bupivacaine 0.5% + 1 cc Fentanil) then in supine position they will be anesthetized generally. Introperative bleeding volume, hemodynamic condition = mean blood pressure, heart rate, and first post operative pain scale based on VAS & amount of morphine administration will be documented.
Category
Treatment - Drugs

2

Description
Control group will only be anesthetized generally. Introperative bleeding volume, hemodynamic condition = mean blood pressure, heart rate, and first post operative pain scale based on VAS & amount of morphine administration will be documented.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Mohammadreza Khajavi M.D.
Street address
Imam Khomeini St. Hasan'abad Sq.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Medical Faculty
Full name of responsible person
Mohammadreza Khajavi
Street address
Keshavarz Bv. Ghods st. Cross
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, Medical Faculty
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Medical Faculty
Full name of responsible person
Mohammadreza Khajavi M.D.
Street address
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City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, Medical Faculty
Proportion provided by this source
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
Tehran University of Medical Sciences
Full name of responsible person
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Position
Associatr Professor
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Person responsible for scientific inquiries

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Anesthesiology assistant

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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