

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

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

#### Protocol summary

imanifar@sina.tums.ac.ir

#### 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 generally. In the control group patients will only be anesthetized generally in the same way that the Intervention group will be performed.

#### 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

#### 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)

#### Phone

+98 21 4469 0816

#### Email address

#### 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

807/130/90/3

## 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 Fentanyl) then in supine position they will be anesthetized generally. Intraoperative 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. Intraoperative 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

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*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammadreza Khajavi M.D.

##### Position

Associate Professor

##### Other areas of specialty/work

##### Street address

Keshavarz Bv. Ghods st. Cross

##### City

Tehran

##### Postal code

##### Phone

+98 21 63120

##### Fax

##### Email

khajavim@tums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, Medical Faculty

**Full name of responsible person**

Mohammad Amir Asadian M.D.

**Position**

Anesthesiology assistant

**Other areas of specialty/work****Street address**

Imam Khomeini St. Hasan'abad Sq.

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 63120

**Fax****Email**

ehsani@itc.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, Medical Faculty

**Full name of responsible person**

Farsad Imani M.D.

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Imam Khomeini St. Hasan'abad Sq.

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 63120

**Fax****Email**

imanifar@tums.ac.ir

**Web page address**

## 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*