

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical Trial of The Effect of Low Dose Ketamine to Prevent Hypotension While Changing Position After Induction of Anesthesia in Patients Undergoing Lumbar Discectomy

Protocol summary

Summary

1) Objectives :Clinical Trial of The Effect of Low Dose Ketamine on Blood Pressure During Positioning After Induction of Anesthesia in Patients Undergoing Lumbar Discectomy ,Clinical Trial of The Effect of Placebo on Blood Pressure During Positioning After Induction of Anesthesia in Patients Undergoing Lumbar Discectomy , Comparison of the Blood Pressure Reduction after Induction of Anesthesia in Two Groups 2) Design: Patients Undergoing Lumbar Discectomy , in Two Groups Ketamine and Placebo , 42 Patient in each Group , Double Blind , Single Center, Recruiting, Randomisation by Random number tables, 3) Setting and conduct: Induction in All Patients will be similar including Midazolam 0.03 mg/kg, Fentanyl 2 mcg/kg, Propofol 1 to 2.5 mg/kg and Atracurium 0.5 mg/kg . After Induction and Intubation, in Ketamine Group 0.5 mg/kg and in Placebo Group Normal Saline with the same volume will be injected . After 90 Seconds to reach the Peak Effect of Ketamine All the Patients with a similar technique will be Positioned. Systolic , Diastolic and Mean Arterial Blood Pressure will be recorded Preoperative , Pre Intubation , one minute after Intubation , before Positioning , Immediately after Positioning the Patient from Supine to Prone Position , then every 2 minute until 10 minutes after Positioning . In the Case of Hypotension more than 20 percent Ephedrine 5 mg (Heart Rate Less than 100/min) or Phenylephrine 50 to 100 microgram (Heart Rate more than 100/min) will be used . 4) Participants Inclusion Criteria: Patients candidated for Lumbar Discectomy, Age between 20 to 40 year with ASA(American Society of Anesthesiologists) Class I, Exclusion Criteria: History of Cardiovascular Drugs usage, Emergency Procedures, Body Mass Index more than 40. 5) Intervention: 1- Midazolam 0.03 mg/kg, Fentanyl 2 mcg/kg, Propofol 1 to 2.5 mg/kg and Atracurium 0.5 mg/kg and Endotracheal Intubation , Ketamine 0.5 mg/kg

1.5 minutes before Positioning The Patient from Supine to Prone Position , 2- Midazolam 0.03 mg/kg, Fentanyl 2 mcg/kg, Propofol 1 to 2.5 mg/kg and Atracurium 0.5 mg/kg and Endotracheal Intubation , Placebo with the same volume (Normal Saline) 1.5 minutes before Positioning The Patient from Supine to Prone Position , 6) main outcome measures: Blood Pressure changes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062726328N2**

Registration date: **2016-08-25, 1395/06/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-25, 1395/06/04

Registrant information

Name

Masoud Parish

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of The Effect of Low Dose Ketamine to Prevent Hypotension While Changing Position After Induction of Anesthesia in Patients Undergoing Lumbar Discectomy

Public title

The effect of Low -dose ketamine to prevent hypotension due to positioning after induction of general anesthesia in lumbar discectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients candidated for Lumbar Discectomy, Age between 20 to 40 year with ASA(American Society of Anesthesiologists) Class I, Exclusion Criteria: History of Cardiovascular Drugs usage, Emergency Procedures, Body Mass Index more than 40

AgeFrom **20 years** old to **40 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **84****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Random Number Table

Secondary Ids

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Shohada Hospital, Yaghchian, Golshahr Avenue, Tabriz, Iran

City

Tabriz

Postal code**Approval date**

2016-06-13, 1395/03/24

Ethics committee reference number

IR.TBZMED.REC.1395.234

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

Hypotension

ICD-10 code

I95.2

ICD-10 code description

Complications of medical and surgical care

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

Diastolic Blood Pressure

Timepoint

Preoperative , Pre Intubation , one minute after Intubation , before Positioning , Immediately after Positioning the Patient from Supine to Prone Position , then every 2 minute until 10 minutes after Positioning

Method of measurement

mmHg using Non Invasive Blood Pressure Technique by Monitoring Device

2**Description**

Mean Arterial Pressure

Timepoint

Preoperative , Pre Intubation , one minute after Intubation , before Positioning , Immediately after Positioning the Patient from Supine to Prone Position , then every 2 minute until 10 minutes after Positioning

Method of measurement

mmHg using Non Invasive Blood Pressure Technique by Monitoring Device

3**Description**

Systolic Blood Pressure

Timepoint

Preoperative , Pre Intubation , one minute after Intubation , before Positioning , Immediately after Positioning the Patient from Supine to Prone Position , then every 2 minute until 10 minutes after Positioning

Method of measurement

mmHg using Non Invasive Blood Pressure Technique by Monitoring Device

4

Description

Heart Rate

Timepoint

Preoperative , Pre Intubation , one minute after Intubation , before Positioning , Immediately after Positioning the Patient from Supine to Prone Position , then every 2 minute until 10 minutes after Positioning

Method of measurement

Beat/min

Secondary outcomes

empty

Intervention groups

1

Description

Intervention by drug includes ketamine 0.5 mg/kg 1.5 minutes before positioning of the patient from supine to prone

Category

Treatment - Drugs

2

Description

In control group Normal Saline with the same volume will be used 1.5 minutes before positioning of the patient from supine to prone position

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Parish Masoud

Street address

Shohada Hospital, Golghasht Avenue, Yaghchian, Tabriz, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Parish Masoud

Street address

Shohada Hospital, Golshahr Avenue, Yaghchian, Tabriz, Iran

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Parish Masoud

Position

Anesthesiologist/Associate Professor

Other areas of specialty/work

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Full name of responsible person

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Position

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

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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