Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Hemodynamic changes after general anesthesia with isoflurane compared with propofol in Lumbar disc in prone position

Protocol summary

Study aim
Evaluation of hemodynamic changes after general anesthesia with isoflurane compared with propofol in lumbar disc in prone position
Design
A randomized clinical trial, With parallel groups, No blinding, three-phase, Randomized on 64 patients.
Settings and conduct
The study population was patients aged 20-65 years who are candidates for elective lumbar disc surgery referred to Ayatollah Rouhani Hospital in Babol. Patients are randomly divided into two intervention groups using a random number table by computer.
Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 20-65 years old؛ Elective candidate for lumbar disc surgery؛ The american society of anesthesiologists (ASA) class I&II (Grade 1: no cardiovascular, respiratory, glandular and Grade 2: Controlled diabetes) Exclusion Criteria: Drug addiction؛ BMI > 30 Kg/m2؛ Patients with airway problems؛ Patients with mental disorders
Intervention groups
Intervention group 1: Induction of anesthesia and prone position of morphine 1 mg/kg will be given and to continue and maintain anesthesia 100-150 µg/ kg/ min propofol 10% infusion. Intervention group 2: Induction of anesthesia and prone position of morphine will be given 1 mg / kg and 1.5-1% isoflurane will be prescribed to continue and maintain anesthesia.
Main outcome variables
Hemodynamic changes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191026045245N2**
Registration date: **2021-09-12, 1400/06/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-12, 1400/06/21**
Update count: **0**
Registration date
2021-09-12, 1400/06/21

Registrant information
Name
Mohsen Daghmehchi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3233 8301
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m.daghmehchi@mubabol.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-11, 1400/06/20
Expected recruitment end date
2022-09-11, 1401/06/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Hemodynamic changes after general anesthesia with isoflurane compared with propofol in Lumbar disc in prone position

Public title
Hemodynamic changes after general anesthesia
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-65 years old Elective candidate for lumbar disc surgery The American Society of Anesthesiologists (ASA) class I&II (Grade 1: No cardiovascular, respiratory, glandular and Grade 2: Controlled diabetes)

Exclusion criteria:

Drug addiction BMI > 30 Kg/m2 Patients with airway problems Patients with mental disorders

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to two groups of 32 using 4 blocks and 16 blocks with a ratio of 1: 1. The free website www.randomization.com will be used to generate the allocation sequence. The resulting sequence will be written on separate sheets and placed in sealed envelopes and will be provided to the lead researcher for study.

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 Babol University of Medical Siences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.MUBABOL.REC.1400.147

Health conditions studied

1

Description of health condition studied

Lumbar disc

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood Pressure

Timepoint

Before induction of anesthesia, after induction of anesthesia and during the operation every 30 minutes, after octopus of the patient and in recovery every 15 minutes

Method of measurement

Monitoring of blood pressure, mm Hg

2

Description

Heart Rate

Timepoint

Before induction of anesthesia, after induction of anesthesia and during the operation every 30 minutes, after octopus of the patient and in recovery every 15 minutes

Method of measurement

Number per minute

3

Description

O2 saturation

Timepoint

Before induction of anesthesia, after induction of anesthesia and during the operation every 30 minutes, after octopus of the patient and in recovery every 15 minutes

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Induction of anesthesia and prone position of morphine (Exir company) 1 mg/kg will be given and to continue and maintain anesthesia 100-150 µg/ kg/ min propofol (Aburaihan company) 10% infusion.

Category
Treatment - Drugs

2

Description
Intervention group: nduction of anesthesia and prone position of morphine (Exir company) 1 mg/kg will be given and to continue and 1.5-1% isoflurane (Aburaihan company) will be prescribed to continue and maintain anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Parviz Amri
Street address
Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
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rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Mohsen Daghmehchi
Position
Assisstant professor of anesthesia
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is still no plan for its publish.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available