

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

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

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of hemodynamic changes after general anesthesia with isoflurane compared with propofol in lumbar disc in prone position

Last update: **2021-09-12, 1400/06/21**

Update count: **0**

Registration date

2021-09-12, 1400/06/21

Design

A randomized clinical trial, With parallel groups, No blinding, three-phase, Randomized on 64 patients.

Registrant information

Name

Mohsen Daghmehchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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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.

Recruitment status

Recruitment complete

Funding source

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

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

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.

Scientific title

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

Main outcome variables

Hemodynamic changes

Public title

Hemodynamic changes after general anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045245N2**

Registration date: **2021-09-12, 1400/06/21**

Purpose

Treatment

IR.MUBABOL.REC.1400.147

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 Sciences

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

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: induction 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

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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

Assistant professor of anesthesia

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Mohsen Daghmehchi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Mohsen Daghmehchi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street addressAyatollah Rouhani Hospital, Daneshgah Square,
Ganjafrooz Avenue**City**

Babol

Province

Mazandaran

Postal code**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