

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of hemodynamic changes and complications of endotracheal intubation with insertion of laryngeal mask airway(LMA) in patients undergoing lumbar disc surgery in prone position

Protocol summary

Study aim

Comparison of Hemodynamic Changes and Complications of Laryngeal Muscle Ligation (LMA) Intubation in Patients Undergoing Lumbar Disc Surgery

Design

In this single-blind randomized clinical trial, patients with ASA Class I, II aged 18-55 years who referred to the operating room of Kashan Shahid Beheshti Hospital for laminectomy in 1997-98,

Settings and conduct

Operating Room of Kashan Shahid Beheshti Hospital

Participants/Inclusion and exclusion criteria

Patients Referred to the Operating Room of Shahid Beheshti and Naghavi Hospitals of Kashan in 1398-1989 with ASA Class I, II, Inclusion Criteria for Lumbar Disc Surgery

Intervention groups

The intervention of this study is the airway device that will be one of the two endotracheal tube or laryngeal mask devices during anesthesia. Patients are randomly selected for the airway and patients are not aware of the type of airway used.

Main outcome variables

ASA class, age, sex, heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP), arterial blood oxygen saturation (SPO2), expired carbon dioxide (ETCO2), maxillary inspiratory pressure (PIP), sore throat, Intubation failure, noise and cough violence, laryngospasm, nausea and vomiting

General information

Reason for update

Change in the start and end date of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045877N1**

Registration date: **2020-01-01, 1398/10/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-07, 1398/10/17**

Update count: **1**

Registration date

2020-01-01, 1398/10/11

Registrant information

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Hoodsa Soroushnia

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes and complications of endotracheal intubation with insertion of laryngeal mask airway(LMA) in patients undergoing lumbar disc surgery in prone position

Public title

hemodynamic changes and complications of endotracheal intubation with insertion of laryngeal mask airway(LMA)

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 55 years Candidate for lumbar disc surgery Anesthesia risk in terms of ASA class I, II classification NPO 6 to 8 hours BMI greater than 18 and less than 30

Exclusion criteria:

Patients with a nasal-gastric tube Patients with the possibility of difficult intubation Patients with preoperative sore throat Patients taking sedative and analgesic drugs Uncontrolled diabetes and uncontrolled hypertension No informed consent to participate in the study

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with ASA Class I, II who referred to the operating room of Kashan Shahid Beheshti Hospital for laminectomy were randomly assigned into two groups of 35 each.

Blinding (investigator's opinion)

Single blinded

Blinding description

After patients enter the operating room and obtain consent to participate in the study and have a vein in a healthy hand and a Ringer's serum connection, the patient is completely blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kashan university of medical sciences

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Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

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Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.082

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

Patients undergoing lumbar disc surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Comparison of hemodynamic changes and complications of intubation in patients undergoing lumbar disc surgery

Timepoint

2, 4, 6, 12 and 24 hours after patient transfer to ward

Method of measurement

Electrocardiographic monitoring, non-invasive automatic barometer and oximeter pulse

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients with ASA Class I, II

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan Martyr Beheshti and Naghavi Hospitals

Full name of responsible person

Mohammad Saadati

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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
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Hoodsa Soroushnia
Position
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Latest degree
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as pipe and chip information, can be shared.

When the data will become available and for how long

Start access period 1 month after publishing results

To whom data/document is available

researchers

Under which criteria data/document could be used

With the permission of the person responsible for the unused use plan.

From where data/document is obtainable

person responsible

What processes are involved for a request to access data/document

Email to responsible

Comments