Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Name
Hoodsa Soroushnia

Name of organization / entity

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Iran (Islamic Republic of)

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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
Street address
Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan
City
Kashan
Province
Isfehan
Postal code
8711111111
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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Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan
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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
Kashan University of Medical Sciences
Full name of responsible person
Hoodsa Soroushnia
Position
Resident
Latest degree
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Person responsible for updating data

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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