Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between three methods of administration Dexmedetomidine on hemodynamic responses to Laryngoscopy and intubation; A Randomized Clinical Trial

Protocol summary

Study aim

Comparison between three methods of administration dexmedetomidine on hemodynamic responses to laryngoscopy and intubation

Design

Double-Blind Randomized Clinical Trial, Phase 3 on 120 patients, Web-based randomization software was used for randomization.

Settings and conduct

The present study will be conducted in the context of Reduction of hemodynamic changes in 120 patients aged 20-60 years who are candidates for surgery at Imam Ali Hospital. Patients are divided into four groups in a blocked random allocation using the web-based system. Hemodynamic evaluation of patients will be done by heart monitoring tool, in the first 5 minutes after intubation, every 1 minute and then in minutes of 7 and 10. for blinding, the patients, the surgeon, and the person performing the evaluation at different intervals will be blinded to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be candidate for surgery under general anesthesia. Do not have respiratory diseases. The patient must not have any intranasal lesions. Do not have heart diseases. Exclusion criteria: Do not be allergic to the drugs in the study. The patient has an unanticipated difficult airway.

Intervention groups

The first group (DIV group): In this group, patients will receive dexmedetomidine intravenously at a dose of 0.5µ/kg by infusion pump before induction of anesthesia. The second group (DIN group): in this group, the patients will receive dexmedetomidine in the amount of 1 µg/kg intranasally. The third group (DNE): In this group, patients will receive 1 µg/kg of dexmedetomidine diluted with 3 to 4 ml of 0.9% normal saline before induction of anesthesia in the form of nebulization. The fourth group (control group): In this group, all the interventions that are done for other groups will be performed with normal saline in equal volumes.

Main outcome variables

hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141001019359N15**
Registration date: **2022-11-04, 1401/08/13**
Registration timing: **prospective**

Last update: **2022-11-04, 1401/08/13**
Update count: **0**

Registration date

2022-11-04, 1401/08/13

Registrant information

Name

Hossein Zeraati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3151 0000

Email address

zeraatih911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-20, 1401/08/29

Expected recruitment end date

2023-04-18, 1402/01/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between three methods of administration Dexmedetomidine on hemodynamic responses to Laryngoscopy and intubation; A Randomized Clinical Trial

Public title
Simultaneous effect of three dexmedetomidine administration methods on hemodynamic responses following laryngoscopy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The Patient must be between 20 and 60 years old ASA physical status I-II The Patient must not have any intranasal lesions The patient must not have cardiovascular problems The patient must not have asthma or respiratory illness
Exclusion criteria:
Patients who are addictive or have drug abuse Patients with an unanticipated difficult airway.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling in this study will be that first in order to enter the study patients will be in the form of non-random sampling of the type "available" and then divide them into three intervention groups by randomly assigned blocking using a web-based system. Random blocking at www.randomization.com will be done in 15 blocks of 8. So that in each block, there are two people in the first group (DIV), two people in the second group (DIN) , two people in the third group (DNE) and two people in forth group (C). After a random sequence was identified in all blocks, cards were written by writing DIV, DIN, DNE and C to indicate which group each patient was assigned to, and by someone other than the research team from 1 to 120 in all blocks, respectively. They are numbered and these cards are placed in sealed non-transparent envelopes, respectively. Then, in order to hide the random allocation, when the patient visits, the opaque sealed envelope will be opened and then one by one, it will be determined for each sample of the relevant group.
Blinding (investigator's opinion)
Double blinded
Blinding description
None of the participants in the study will be aware of the randomization list, and in order to conceal the randomization process, the groups will be placed in closed envelopes in the reception area and will be assigned to the eligible individuals who enter the study. Also, in order to blind the patients to the study groups, in addition to the specific intervention of each group, the interventions of other groups will be performed with an equal volume of normal saline.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences
Street address
Vice Chancellor for Research of North Khorasan University of Medical Sciences, Bojnurd
City
Bojnurd
Province
North Khorasan
Postal code
9416678894
Approval date
2022-10-20, 1401/07/28
Ethics committee reference number
IR.NKUMS.REC.1401.060

Health conditions studied

1

Description of health condition studied
Hemodynamic variables
ICD-10 code
T88.59
ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description

Changes in hemodynamic parameters during intubation

Timepoint

After induction of anesthesia, in the first 5 minutes after intubation, every 1 minute after induction and on minutes 7 and 10

Method of measurement

Using the monitoring device

Secondary outcomes

1

Description

Hemodynamic responses during skin incision

Timepoint

Skin incision time

Method of measurement

Patients' response to skin incision will be recorded as yes/no (no if less than 20% changes in hemodynamic parameters and yes if more than 20% changes are observed in them)

2

Description

Patient's sedation status

Timepoint

At the entering of the operating room and then 40 minutes after the interventions

Method of measurement

Ramsey's sedation scale

3

Description

Extubation time after reversal of neuromuscular relaxant

Timepoint

From the time of administration of Neostigmine to removal of the endotracheal tube

Method of measurement

chronometer

4

Description

Post-operative nausea and vomiting

Timepoint

2 hours after the operation

Method of measurement

In the form of presence or absence

5

Description

Sore throat after operation

Timepoint

2 hours after the operation

Method of measurement

In the form of presence or absence

Intervention groups

1

Description

Intervention group DIV: In this group, Patients will receive Dexmedetomidine intravenously at a dose of 0.5µ/kg by infusion pump within 40 minutes before induction of anesthesia.

Category

Prevention

2

Description

Intervention group DIV: In this group, Patients will receive 1 µg/kg of undiluted form of Dexmedetomidine Intranasally.

Category

Prevention

3

Description

Intervention group DNE: This group of patients will receive 1 µg/kg of Dexmedetomidine diluted with 3 to 4 ml of 0.9% normal saline as a Nebulization 40 minutes before anesthesia induction.

Category

Prevention

4

Description

Control group: In this group, all interventions that are done for other groups will be performed with normal saline in equal volumes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Hospital

Full name of responsible person

Ali Esmaeili

Street address

Emam Ali hospital, North Khorasan, Bojnurd, Iran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bojnourd 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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Ali Esmaeili
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available