Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effect of two different doses of dexmedetomidine intranasal on the cardiovascular response to laryngoscopy and endotracheal intubation

Protocol summary

Study aim
Determination of the effect of 2 different doses of dexmedetomidine intranasal on cardiovascular response to laryngoscopy and endotracheal intubation

Design
Clinical trial with control group, triple blind, randomized, phase 3 on 90 patients

Settings and conduct
The study of a triple blind randomized clinical trial with a control group during the years 1401-1400 Will be performed at Al-Zahra Medical Center in Isfahan. The person collecting the information does not know the study group, nor does the statistician Does not know the study group

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-65 years II, I ASA (American Anesthesia Association classification based on patients' physical condition) without airway anomaly, elective surgery Inclusion criteria: History of drug sensitivity, pregnancy, Difficult airway , ECG block, BMI> 30, history of obstruction Nasopharyngeal ducts

Intervention groups
Group 1: 1 µg/kg intranasal dexmedetomidine at a concentration of 100 µg/ml in a 1cc syringe after injection of anesthetic drug. Group 2: 2 µg/kg intranasal dexmedetomidine at a concentration of 100 µg/ml in a 1cc syringe after injection of anesthetic drug. Group 3: Normal saline with a volume equivalent to groups 1 and 2 intranasally.

Main outcome variables
Heart rate, systolic blood pressure, diastolic blood pressure, Mean arterial pressure, percentage of oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054628N1**
Registration date: **2022-04-30, 1401/02/10**
Registration timing: **prospective**

Last update: **2022-04-30, 1401/02/10**
Update count: **0**

Registration date
2022-04-30, 1401/02/10

Registrant information

Name
Zahra Maghsoudi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3662 4796

Email address
zahra.m7596@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-21, 1401/02/31

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of two different doses of dexmedetomidine intranasal on the cardiovascular response to laryngoscopy and endotracheal intubation

Public title

The effect of dexmedetomidine on cardiovascular response

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Elective surgery No airway abnormalities Requires endotracheal intubation under general anesthesia

Exclusion criteria:

History of allergy to the studied drug Difficult Airway Heart block in ECG BMI>30 History of obstruction of the nasopharyngeal ducts Pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the simple randomization method of block randomization (block randomization) we will use. Blocking is usually in order Balance the number of samples assigned to each group To be used in the study. This feature helps researchers to Items that require intermediate analyzes during the sampling process The number of samples assigned to each of the case groups Study is equal. The size of all the blocks is equal and we are in this We will have a three-group trial of 6 blocks of 15. Randomization tools are also used in sequence generation software Random (software allocation Random) is used that Random sequence generation software in addition to simple randomization capable To generate random sequences by block generation method. For hiding We avoid concealment allocation We use the method used to execute the sequence Random refers to study participants, in a way That before the individual is assigned, the assigned group is not specified. With From opaque envelopes sealed in random sequence (envelopes opaque, sealed, numbered Sequentially) in This method uses each of the random sequences created on a card It is registered and the cards are placed in the letter envelopes in order To be. In order to maintain a random sequence, also on the outer surface of the envelope The numbering is done in the same way. Finally the envelope lid The letters are pasted and placed in a box, respectively. At Time to start registration of participants, based on the order of entry of the company Eligible applicants to open one of the envelopes in order And the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The researcher, patients and project partner who will perform the statistical analysis will not be aware of the study (triole blind). The grouping of patients will be recorded on a sheet and given to one of the project colleagues.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib St., Azadi Square

City

Isfahan

Province

Isfehan

Postal code

8164945813

Approval date

2022-01-17, 1400/10/27

Ethics committee reference number

IR.MUI.MED.REC.1400.748

Health conditions studied

1

Description of health condition studied

Cardiovascular response after laryngoscopy and tracheal intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart Rate

Timepoint

before induction of anesthesia and minutes 1, 3, 5, 10

Method of measurement

Cardiac monitor device

2

Description
Systolic blood pressure
Timepoint
before induction of anesthesia and minutes 1, 3, 5, 10
Method of measurement
In millimeters of mercury using a calibrated barometer

3

Description
Diastolic blood pressure
Timepoint
before induction of anesthesia and minutes 1, 3, 5, 10
Method of measurement
In millimeters of mercury using a calibrated barometer

4

Description
mean arterial pressure
Timepoint
before induction of anesthesia and minutes 1, 3, 5, 10
Method of measurement
In millimeters of mercury using a calibrated barometer

5

Description
Percentage of oxygen saturation
Timepoint
before induction of anesthesia and minutes 1, 3, 5, 10
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
hypotension
Timepoint
Before induction of anesthesia, minutes 1, 3, 5, 10
Method of measurement
In millimeters of mercury using a calibrated barometer

2

Description
hypertension
Timepoint
Before induction of anesthesia, minutes 1, 3, 5, 10
Method of measurement
In millimeters of mercury using a calibrated barometer

3

Description
bradycardia
Timepoint
Before induction of anesthesia, minutes 1, 3, 5, 10
Method of measurement
Cardiac monitor device

4

Description
tachycardia
Timepoint
Before induction of anesthesia, minutes 1, 3, 5, 10
Method of measurement
Cardiac monitor device

Intervention groups

1

Description
Intervention group: 1 µg / kg dexmedetomidine intranasal at a concentration of 100 µg / ml in a 1cc syringe after injection of anesthetic drug
Category
Prevention

2

Description
Intervention group: 2 µg / kg dexmedetomidine intranasal at a concentration of 100 µg / ml in a 1cc syringe after injection of anesthetic drug
Category
Prevention

3

Description
Control group: Normal saline with a volume equivalent to groups 1 and 2 intranasally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
azim honarmand
Street address
Al-Zahra Hospital, Isfahan University of Medical Sciences, Hezar Jerib St., Azadi Square
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Isfahan
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Isfehan
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8164945812
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+98 31 3662 4796
Email
honarmand@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
mojgan mortazavi
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Isfahan University of Medical Sciences., Hezar Jarib St., Azadi Square
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Postal code
8164945811
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Email
mortazavi@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Azim Honarmand
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Maghsoudi
Position
Medical intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jerib St., Azadi Square
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Zahra.m7596@gmail.com

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
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

Title and more details about the data/document
Information on the effectiveness of dexmedetomidine on the cardiovascular response

When the data will become available and for how long
Start the access period up to one year after the results are published

To whom data/document is available
Researchers

Under which criteria data/document could be used
Can be used for secondary studies.

From where data/document is obtainable
Correspond with honarmand@mui.ac.ir.

What processes are involved for a request to access data/document
Will be sent after receiving the email.

Comments