

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 (triple 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

Isfahan

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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8164945812

Phone

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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

Street address

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

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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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Al-Zahra Hospital, Isfahan University of Medical Sciences, Hezar Jarib St., Azadi Square

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Fax**Email**

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Person responsible for scientific 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 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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8164945812

Phone

+98 31 3662 4796

Fax**Email**

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