Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effects of two different doses intranasal Dexmedetomidine on heart rate and blood pressure changes after Laryngoscopy and Endotracheal intubation in patients need of anesthesia before surgery

Protocol summary

Study aim
Comparison of the effects of two different doses intranasal Dexmedetomidine on heart rate and blood pressure changes after Laryngoscopy and Endotracheal intubation in patients need of anesthesia before surgery

Design
This study was conducted in parallel, double-blind, randomized,90 patients who were in the Phase 3 trial were designed.

Settings and conduct
This study was a double-blind clinical trial that was performed on 90 patients undergoing surgery that referred to Al-Zahra hospital. Patients in this study were randomly divided into three groups of 30 patients.Patients in the first group received intranasal dexmedetomidine at a dose of 1µg/kg , and the second group received intranasal dexmedetomidine at a dose of 2µg/kg and control group received normal saline in the form of intranasal .

Participants/Inclusion and exclusion criteria
inclusion criteria: 1)Patients candidate Laryngoscopy and Endotracheal intubation 2)Patients older than 18 yeras old and younger than 65 years old 3)Patients with American society of anesthesiology physical status class 1,2 (ASAI,II) ؛ Exclusion criteria: 1)Head and neck masses 2)Airway malformation 3)Uncontrollable blood pressure(More than 180/110) 4)History of cardiovascular disease 5)History of respiratory disease 6)allergies to the drugs studied 7)Body Mass Index greater than 30

Intervention groups
Initially , informed consent is obtained from the patients. After placing the patients on the operating bed, inclusion of standard monitoring including pulsoximetr , capnograph, electrocardiograph (ECG) and the vital signs are attached.Then intervention group A receives 1µg/kg of intranasal dexmedetomidine and intervention group B receives 2 µg/kg of intranasal dexmedetomidine and control group receives normal saline ,30 minutes before induction of anesthesia inside both nostrils .

Main outcome variables
Blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N15**
Registration date: **2019-07-24, 1398/05/02**
Registration timing: **retrospective**

Last update: **2019-07-24, 1398/05/02**
Update count: **0**

Registration date
2019-07-24, 1398/05/02

Registrant information

Name
Behzad Nazemroaya
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of two different doses intranasal Dexmedetomidine on heart rate and blood pressure changes after Laryngoscopy and Endotracheal intubation in patients need of anesthesia before surgery

Public title

The effects of two different doses dexmedetomidine after Endotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate Laryngoscopy and Endotracheal intubation Patients older than 18 yeras old and younger than 65 years old Patients with American society of anesthesiology physical status class 1,2 (ASAI,II)

Exclusion criteria:

Head and neck masses Airway malformation Uncontrollable blood pressure(More than 180/110) History of cardiovascular disease History of respiratory disease allergies to the drugs studied Body Mass Index greater than 30(BMI>30)

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
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to three groups A, B, C using the Random Allocation computer software

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo are prepared in one form and in the form of a volume in the syringe by the researcher, and the hemodynamic changes are monitored and recorded, so the attending and the clinical caregiver and the evaluator and data analyser do not understand the type of medication and the investigator deciphers the codes after data analysis.

Placebo

Used

Assignment

Parallel

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

Hezar Jarib street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2017-05-28, 1396/03/07

Ethics committee reference number

IR.MUI.REC.1396.3.794

Health conditions studied

1

Description of health condition studied

Blood pressure

ICD-10 code

R03.0

ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

2

Description of health condition studied

Heart rate

ICD-10 code

R00.0

ICD-10 code description

Tachycardia, unspecified

Primary outcomes

1

Description

Heart rate changes

Timepoint

Before the intervention, 1 ,3, 5, 10 minutes after

laryngoscopy

Method of measurement

Heart monitoring

2

Description

Systolic blood pressure

Timepoint

Before the intervention, 1 ,3, 5, 10 minutes after laryngoscopy

Method of measurement

Non invasive blood pressure monitor

3

Description

Diastolic blood pressure

Timepoint

Before the intervention, 1 ,3, 5, 10 minutes after laryngoscopy

Method of measurement

Non invasive blood pressure monitor

4

Description

Mean arterial pressure

Timepoint

Before the intervention, 1 ,3, 5, 10 minutes after laryngoscopy

Method of measurement

Non invasive blood pressure monitor

5

Description

Oxygen saturation

Timepoint

Before the intervention, 1 ,3, 5, 10 minutes after laryngoscopy

Method of measurement

Percent with pulse oximeter

6

Description

Recovery time

Timepoint

From the end of surgery to full consciousness

Method of measurement

Minute with using a chornometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A:Initially , informed consent is obtained from the patients. After placing the patients on the operating bed, inclusion of standard monitoring including pulsoximetr , capnograph, electrocardiograph (ECG) and the vital signs are attached . In group A, 1µg•kg-1 of intranasal dexmedetomidine is given 30 minutes before induction of anesthesia inside both nostrils. Median arterial blood pressure, heart rate, systolic blood pressure and diastolic blood pressure at one, three, five and Ten minutes after intubation are recorded .

Category

Treatment - Drugs

2

Description

Intervention group B:Initially , informed consent is obtained from the patients. After placing the patients on the operating bed, inclusion of standard monitoring including pulsoximetr , capnograph, electrocardiograph (ECG) and the vital signs are attached . In group B, 2µg•kg-1 of intranasal dexmedetomidine is given 30 minutes before induction of anesthesia inside both nostrils. Median arterial blood pressure, heart rate, systolic blood pressure and diastolic blood pressure at one, three, five and Ten minutes after intubation are recorded .

Category

Treatment - Drugs

3

Description

Control group: Initially , informed consent is obtained from the patients. After placing the patients on the operating bed, inclusion of standard monitoring including pulsoximetr , capnograph, electrocardiograph (ECG) and the vital signs are attached . In group C, normal saline is given 30 minutes before induction of anesthesia inside both nostrils. Median arterial blood pressure, heart rate, systolic blood pressure and diastolic blood pressure at one, three, five and Ten minutes after intubation are recorded .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Behzad Nazemroaya

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Soffeh boulevard, Shahid Keshvari highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Amir Mohammad Ataie

Position
Medical Student/ Intern

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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