Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Studying the bolus dose of Dexmedetomidine effect in attenuating hemodynamic stress response to laryngoscopy and tracheal intubation in hypertensive patients

Protocol summary

Study aim

Assessment of bolus dose of Dexmedetomidine effect in attenuating hemodynamic stress response to laryngoscopy and tracheal intubation in hypertensive patients

Design

A randomized double-blinded clinical trial on 70 patients with or without hypertension as study and control groups. Randomization using Random allocation software allocated to 35 patient groups.

Settings and conduct

The research will be carried out in Urmia Emam Khomeini Hospital, affiliated to Urmia University of Medical Sciences. Dexmedetomidine at 4 microgram per kilogram of body weight concentration prepared in 50 cc syringes will be infused during 10 minutes for the study group and the control group will receive a normal saline infusion. Drug and placebo are indistinguishable. Anesthesia will be induced using 1% propofol until the losing eyelid reflex and Atracurium will be injected at 4mg/Kg dose. After 3 minutes of mask ventilation, the patient will be intubated and hemodynamic changes including heart rate, MAP, DBP, and SBP will be recorded at T0(basic hemodynamics), T1(5 minutes after drug injection)T2(after induction of anesthesia), T3(1 minute after induction), T4(3 minutes after intubation), T5(5 minutes after intubation) and T6(10 minutes after intubation).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Normotensive patients, stage I-II hypertensive patients at age 40-70 Exclusion criteria: patients under age 40 and above 70, stage III hypertension, patient refusal

Intervention groups

The study group patients will get a bolus IV infusion of dexmedetomidine before general anesthesia induction and the control group patients will get normal saline.

Main outcome variables

Systolic, diastolic, mean arterial blood pressure, and heart rate.

General information

Reason for update

Acronym

SBP,DBP,MAP,HR

IRCT registration information

IRCT registration number: **IRCT20151219025600N5**
Registration date: **2024-07-24, 1403/05/03**
Registration timing: **prospective**

Last update: **2024-07-24, 1403/05/03**
Update count: **0**

Registration date

2024-07-24, 1403/05/03

Registrant information

Name

Shahram Shokohi

Name of organization / entity

Urmia University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-31, 1403/05/10

Expected recruitment end date

2025-01-29, 1403/11/10

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

Scientific title
Studying the bolus dose of Dexmedetomidine effect in attenuating hemodynamic stress response to laryngoscopy and tracheal intubation in hypertensive patients

Public title
Bolus dose of dexmedetomidine effect on hemodynamic response to laryngoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
normotensive Patients Stage I-II hypertensive patients patients at age 40-70
Exclusion criteria:
Difficult intubation BMI more than 30 Patient receiving Clonidine Pregnancy Laryngoscopy more than 20 seconds Emergency surgery Patients with heart blocks ASA class III and more Patients with pheochromocytoma Patients with thyroid disorders Patients with neuropathy
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients by block randomization will be allocated to equal groups of study and placebo using "random allocation" software providing computerized numbers. The numbers will be written on envelopes containing the drug or placebo notes and will be delivered to the anesthesia nurse as sealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the researcher who evaluates the outcomes will not informed of patients allocation to the study and control groups. Both drug and placebo will be colorless prepared and injected in 50 cc syringes at equal volumes. Each patient will allocate a number using randomization allocation software in sealed envelopes containing the drug or placebo delivered to the anesthesia nurse. The researcher will not be informed of syringe content.
Placebo
Used
Assignment
Other
Other design features
no more explanation

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Urmia Univerity of Medical Scineces-Imam Khomeini University Hospital
Street address
Imam Khomein teaching hospitalT Ershad street
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Urmia
Province
West Azarbaijan
Postal code
5715789397
Approval date
2024-02-28, 1402/12/09
Ethics committee reference number
IR.UMSU.HIMAM.REC.1402.162

Health conditions studied

1

Description of health condition studied
Arterial Blood Pressure
ICD-10 code
I10
ICD-10 code description
Hypertension (arterial)(benign)(essential)(malignant)(primary)(systemic)

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
At time zero(basic hemodynamics),T1(5 minutes after drug or placebo injection),T2(after induction of general anesthesia) T3(one minute after tracheal intubation),T4(3 minutes after intubation) T5(5 minutes after intubation) T6(10 minutes after intubation)
Method of measurement
Measuring using electronic cardiovascular monitoring device

2

Description
Diastolic blood pressure
Timepoint
At time zero(basic hemodynamics),T1(5 minutes after drug or placebo injection),T2(after induction of general anesthesia) T3(one minute after tracheal intubation),T4(3 minutes after intubation) T5(5 minutes after intubation) T6(10 minutes after intubation)
Method of measurement
Measuring using electronic cardiovascular monitoring device

3

Description
Mean arterial pressure
Timepoint
At time zero(basic hemodynamics),T1(5 minutes after drug or placebo injection),T2(after induction of general anesthesia) T3(one minute after tracheal intubation),T4(3 minutes after intubation) T5(5 minutes after intubation) T6(10 minutes after intubation)
Method of measurement
Measuring using electronic cardiovascular monitoring device

4

Description
Heart rate
Timepoint
At time zero(basic hemodynamics),T1(5 minutes after drug or placebo injection),T2(after induction of general anesthesia) T3(one minute after tracheal intubation),T4(3 minutes after intubation) T5(5 minutes after intubation) T6(10 minutes after intubation)
Method of measurement
Measuring using electronic cardiovascular monitoring device

Secondary outcomes

1

Description
Hypnotic drug(propofol) induction dose in patients with hypertensive disease
Timepoint
At the end of anesthesia induction
Method of measurement
Propofol dose needed for induction of anesthesia as milligram

Intervention groups

1

Description
Intervention group:Patients without or with hypertension class I-II at age 40-70
Category
Treatment - Drugs

2

Description
Control group: Patients without or with hypertension class I-II at age 40-70 receiving placebo (normal saline infusion)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini University hospital of Urmia
Full name of responsible person
Shahram Shokohi
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Ershad street, Modarres Boulvard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Gholizade
Street address
Emergency street
City
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Province
West Azarbaijan
Postal code
5714783734
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research@umsu.ac.ir
Grant name
Non-use of financial grants
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Shahram Shokohi
Position
Assisstant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic and primary outcome data without identification can be shared.
When the data will become available and for how long
Research data will be available until April 2025 and there after.
To whom data/document is available
Only medical academic researchers have access to data.
Under which criteria data/document could be used

No other condition is necessary for access.

From where data/document is obtainable

Correspondent researcher Shahram Shokoohi shokohi.sh@umsu.ac.ir

What processes are involved for a request to access data/document

Write to the corresponding researcher Shahram Shokoohi shokohi.sh@umsu.ac.ir

Comments

no more explanation