

# 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

+98 44 3346 8967

##### Email address

shokohi.sh@umsu.ac.ir

##### 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

**City**

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

#### **Street address**

Ershad street, Modarres Boulevard

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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

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West Azarbaijan

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#### **Email**

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**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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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