

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the effects of dexmethomedin and midazolam on hemodynamic changes during extubation of patients with a history of hypertension candidates for non-emergency orthopedic surgery

#### Protocol summary

##### Study aim

Comparison of the effects of dexmethomedin and midazolam on hemodynamic changes during extubation of patients with a history of hypertension candidates for non-emergency orthopedic surgery

##### Design

This study will be a randomized, single-blind clinical trial with parallel groups in phase 3-2, which will be divided into two groups of 50 people online.

##### Settings and conduct

In this study, 100 candidates for general anesthesia in Shohada Hospital (Tabriz) will be included in the study and will be randomly divided into two groups with the help of online software. Prior to extubation, patients in the intervention group will be injected with dexmedetomidin and in the control group with midazolam; The data analyzer will be unaware of the type of grouping and will be blind during the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) Patients candidates for orthopedic surgery require general anesthesia (2) History of hypertension with the approval of a cardiologist (3) Use of antihypertensive drugs and non-inclusion criteria: (1) Blood pressure Uncontrolled over (2) patients with difficult intubation (3) pregnant women.

##### Intervention groups

A total of 100 orthopedic surgery candidates will be included in this study and will be divided into two groups after randomly assigned online. Patients in the intervention group will receive 0.6 mg / kg body weight per hour before the extubation intervention, and patients in the control group will receive midazolam 0.02 mg / kg body weight ten minutes before extubation. Will receive as a bolus

##### Main outcome variables

Hemodynamic status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190325043107N26**

Registration date: **2022-01-21, 1400/11/01**

Registration timing: **prospective**

Last update: **2022-01-21, 1400/11/01**

Update count: **0**

##### Registration date

2022-01-21, 1400/11/01

##### Registrant information

##### Name

Mehdi Khanbabayi Gol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

khanbabayimehdi69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-19, 1400/11/30

##### Expected recruitment end date

2022-04-19, 1401/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effects of dexmethomedin and midazolam on hemodynamic changes during extubation of patients with a history of hypertension candidates for non-emergency orthopedic surgery

## Public title

Comparison of dexmetomedin and midazolam on hemodynamic changes during extubation of patients with a history of hypertension

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Candidates for orthopedic surgery require general anesthesia History of high blood pressure with the approval of a cardiologist Taking medications to control high blood pressure

### Exclusion criteria:

Uncontrolled high blood pressure Patients with difficult intubation Pregnant women

## Age

From **18 years** old to **75 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be placed in one of two groups of midazolam or dexmethomedin, respectively, according to the purification list prepared with the help of Online statistical software (WWW.Randomizer.org). In this software, 100 people will be determined; Then, the patients' details will be entered into this software by entering the study and will be divided into two relevant groups by the software.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The statistical consultant will be unaware of the grouping of patients, so he will be blind during the study.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

#### Street address

Imam Reza Hospital, Azadi Ave

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5165665631

### Approval date

2021-12-13, 1400/09/22

### Ethics committee reference number

IR.TBZMED.REC.1400.920

## Health conditions studied

## 1

### Description of health condition studied

Hemodynamic status

### ICD-10 code

R03.0

### ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

## Primary outcomes

## 1

### Description

Hemodynamic status

### Timepoint

Every minute for ten minutes

### Method of measurement

A mercury sphygmomanometer will be used to measure blood pressure and a pulse oximeter will be used to measure heart rate.

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Patients will receive dexmedetomidine at a rate of 0.6 mg /kg per hour ten minutes before extubation and their hemodynamic status (blood pressure and heart rate) for one minute every ten minutes after extubation. The load will be measured.

### Category

Prevention

## 2

### Description

Control group: Patients will receive 0.02 mg /kg in the form of bolus in the ten minutes before extubation and their hemodynamic status (blood pressure and heart rate) for ten minutes after each extubation. It will be measured once a minute.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shohada Hospital

**Full name of responsible person**

Masoud Parish

**Street address**

Shohada Hospital, Azadi Ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

6165665631

**Phone**

+98 41 3335 5921

**Email**

Drparishm@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahabi

**Street address**

Tabriz University of Medical Sciences , Azadi Ave

**City**

Tabriz

**Province**

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**Email**

Shahabi.p@hotmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Masoud Parish

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shohada Hospital, Azadi Ave

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Masoud Parish

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

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**Email**

Khanbabayimehdi69@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Khanbabayi Gol

**Position**

MSc in Nursing Education

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Fax**

**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**

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