

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

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Drparishm@yahoo.com

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

Anesthesiology

Street address

Shohada Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Drparishm@yahoo.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

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

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