

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of hemodynamic response during anesthesia induction using Dexmedetomidine and Midazolam in hypertensive patients undergoing orthopedic surgery

Protocol summary

Study aim

Evaluation of hemodynamic changes after dexmedetomidine and midazolam injection in hypertensive anesthesia patients

Design

Clinical trial with 2 intervention groups, with parallel groups, double-blind, randomized, phase 2 on 130 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients in Shohada hospital operating room will be randomly divided into two groups based on a random number table. The intervention group 1, received 10 micro gram per kilogram Dexmedetomidine and the intervention group 2, received 0.03 mg / kg Midazolam. Given that the study is double-blind. Both Dexmedetomidine and Midazolam will be administered to the required number by the planter every morning prior to the start of surgery. Envelope A contains a syringe containing Dexmedetomidine and Envelope B contains Midazolam. Each patient will receive these envelopes on the basis of an A or B code, provided by the anesthesiologist who is unaware of the type of drug as the patient is.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 40 to 70 years old; known hypertensive treated patients; candidate for elective orthopedic surgery. Exclusion criteria: patients treated with psychotic drugs; emergency patients; traumatic patients with heavy bleeding; liver and kidney disorders; patients with ischemic heart disease; patients with severe systemic vascular disease.

Intervention groups

Intervention group 1: in the first intervention group, 10 µg / kg dexmedetomidine will be injected 5 minutes before anesthesia. Intervention group 2: in the second intervention group, 0.03 mg / kg midazolam will be

injected 5 minutes before anesthesia.

Main outcome variables

Systolic and diastolic blood pressure; heart rate; saturation of peripheral oxygen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160202026328N6**

Registration date: **2020-11-22, 1399/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-22, 1399/09/02**

Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Masoud Parish

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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parishm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic response during anesthesia induction using Dexmedetomidine and Midazolam in hypertensive patients undergoing orthopedic surgery

Public title

Comparison of hemodynamic changes in hypertensive patients after dexmedetomidine and midazolam injection

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 40 to 70 years old Known hypertensive treated patients Candidate for elective orthopedic surgery

Exclusion criteria:

Patients treated with psychotic drugs Emergency patients Traumatic patients with heavy bleeding Liver and kidney disorders Patients with ischemic heart disease Patients with severe systemic vascular disease

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Through a randomly generated computer-generated list, individuals in 4-person blocks will be assigned to two intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the thesis owner student provides the drugs to the anesthesiologist and is the only person who is not blind to the study. The anesthesiologist, who is in charge of the patient's anesthesia management, injects the drug through coded syringes that have already been prepared by the thesis owner. So that anesthesiologist is unaware of the injected drug to patient during injection. The anesthesia nurse, who is responsible for collecting information and variables from the patient and is unaware of the type of prescribed drug, fills in the checklist during surgery and recovery. The patient is also unaware of the type of Injecting drug.

Placebo

Not used

Assignment

Factorial

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

Faculty of Medicine, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-08-10, 1399/05/20

Ethics committee reference number

IR.TBZMED.REC.1399.540

Health conditions studied**1****Description of health condition studied**

Comparison of hemodynamic changes in anesthetized patients with hypertension following dexmedetomidine and midazolam injection.

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes**1****Description**

Systolic blood pressure

Timepoint

5 minutes before entering the operating room, the moment of entering, 5 minutes after lying down in a relaxed state, immediately after the injection of the intervention drug, 5 minutes after the injection and then every 15 minutes until the end of the operation

Method of measurement

Mercury barometer

2**Description**

Diastolic blood pressure

Timepoint

5 minutes before entering the operating room, the moment of entering, 5 minutes after lying down in a relaxed state, immediately after the injection of the intervention drug, 5 minutes after the injection and then every 15 minutes until the end of the operation

Method of measurement

Mercury barometer

3

Description

Heart rate

Timepoint

5 minutes before entering the operating room, the moment of entering, 5 minutes after lying down in a relaxed state, immediately after the injection of the intervention drug, 5 minutes after the injection and then every 15 minutes until the end of the operation

Method of measurement

Counting in each minutes

4

Description

Saturation of peripheral oxygen

Timepoint

5 minutes before entering the operating room, the moment of entering, 5 minutes after lying down in a relaxed state, immediately after the injection of the intervention drug, 5 minutes after the injection and then every 15 minutes until the end of the operation

Method of measurement

Via the Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: in the first intervention group, 10 µg / kg dexmedetomidine will be injected 5 minutes before anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group 2: in the second intervention group, 0.03 mg / kg midazolam will be injected 5 minutes before anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital, Tabriz University of Medical Sciences

Full name of responsible person

Masoud Parish

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Shohada Hospital, Golshahr Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Jouyban

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Research and Technology deputy, Third floor, the headquarter building No 2, Tabriz University of Medical Sciences, Golgasht street, Tabriz

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research-vice@tbzmed.ac.ir

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
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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

All potential data can be shared after making peoples unrecognizable.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data

From where data/document is obtainable

Dr .Masoud Parish , Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 ,

masoudparish@yahoo.com

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

Applicants will access the data from the present study by

sending an email to the responsible author for a maximum of one week.

Comments