Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 41 3385 5842

Email address
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
Faculity 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

Street address

Shohada Hospital, Golshahr Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3517

Fax

+98 41 3389 3517

Email

masoudparish@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Jouyban

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Fax

+98 41 3335 7310

Email

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

Street address

Shohada Hospital, Golshahr Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3517

Fax

+98 41 3389 3517

Email

masoudparish@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, Golshahr Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3517

Fax

+98 41 3389 3517

Email

masoudparish@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parish Masoud

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shohada Hospital, Golshahr Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3517

Fax

+98 41 3389 3517

Email

masoudparish@yahoo.com

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