Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of The Efficacy And Side Effects of Combined Doses of Dexmedetomidine And Propofol With Isoflurane And Nitrosoxide as a General Anesthetic Preservative in Orthopedic Surgeries

Protocol summary

Study aim

Comparison of the efficacy and side effects of combined doses of dexmedetomidine and propofol with isoflurane and nitrosoxide as a general anesthetic preservative in orthopedic surgeries

Design

Clinical trialwithcontrolgroup,withparallelgroups,doubleblind,randomized,phase 3 on 90 patients. For randomization using a table of random numbers are assigned to three groups A, B and C (30 people in each group). The anesthesia assistant will not know the study groups and the dose of IV and inhaled drugs. The drugs will be prepared by an anesthesiologist using labels A, B and C.

Settings and conduct

This study is a randomized clinical trial to compare the efficacy and side effectsofcombineddosesofdexmedetomidineandpropofol withisofluraneandnitrosoxide as a general anesthetic in orthopedic surgery in patients admitted to medical centers affiliated to the University of Medical Sciences. Mazandaran will be done in 1401. The research environment is the operating room of Imam Khomeini Educational and Medical Center in Sari. The study population consists of patients who are candidates for non-emergency orthopedic surgery under general anesthesia

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-60 years, Class 1 and 2 anesthesia (ASA), Patients with complications such as hypotension, hypertension, bradycardia, pneumothorax, air embolism and decreased arterial oxygen saturation, which are possible side effects of anesthetics. , Do not have. Withdrawal conditions: Emergency surgery, known allergy to the drugs used in

Intervention groups

Patients undergoing intravenous anesthesia using the minimum combined doseofpropofolanddexmedetomidinePatientsundergoingintravenousanesthesia using the maximum combined dose of propofol and dexmedetomidine Patients will undergo inhalation anesthesia using isoflurane and nitrous oxide.

Main outcome variables

Time to wake up from anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210904052371N3**
Registration date: **2022-06-20, 1401/03/30**
Registration timing: **prospective**

Last update: **2022-06-20, 1401/03/30**
Update count: **0**

Registration date

2022-06-20, 1401/03/30

Registrant information

Name
Goli Aezi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3311 9875

Email address
gaezi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Efficacy And Side Effects of Combined Doses of Dexmedetomidine And Propofol With Isoflurane And Nitrosoxide as a General Anesthetic Preservative in Orthopedic Surgeries

Public title

Comparison of The Efficacy And Side Effects of Combined Doses of Dexmedetomidine And Propofol With Isoflurane And Nitrosoxide as a General Anesthetic Preservative in Orthopedic Surgeries

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's desire to participate in the study and gain informed consent Candidate for non-emergency orthopedic surgery under general anesthesia Age between 18-60 years Class 1 and 2 Anesthesia (ASA) Patients who do not have complications such as hypotension, hypertension, bradycardia, pneumothorax, air embolism and decreased arterial oxygen saturation, which is a possible side effect of anesthetics

Exclusion criteria:

Emergency surgery Known allergies to the drugs used in the present study Operation longer than 5 hours Patients during the intervention if acute complications such as hypotension, hypertension, bradycardia, pneumothorax, air embolism and a decrease in arterial oxygen saturation.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are randomly assigned (using a table of random numbers) to three groups A, B and C (30 people in each group). The anesthesia assistant will not know the study groups and the dose of IV and inhaled drugs. The drugs will be prepared by an anesthesiologist using labels A, B and C. They will be provided to the anesthesia assistant in the lower year. B Patients will undergo complete intravenous anesthesia using the maximum combined dose of propofol and dexmedetomidine. In group C, patients will undergo inhalation anesthesia using isoflurane and nitrous oxide.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study will be conducted in a double-blind method, so that neither patients nor the evaluators of the study outcomes are aware of the placement of patients in the study groups. In addition, fair people are placed in groups. Syringes prepared with different concentrations that have reached the same volumes with normal saline for bolus injection and Prepared microstructures with different concentrations (2 groups of maximum and minimum dose) that have reached the same volumes with normal saline, for infusion during operation A low-year resident or anesthesiologist present at the patient's bedside who do not know the concentration of the drug And record only clinical signs and vital signs

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

33131 - 48166

Approval date

2022-04-13, 1401/01/24

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1401.008

Health conditions studied

1

Description of health condition studied

Depth of anesthesia

ICD-10 code
Y84
ICD-10 code description
Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Time to wake up from anesthesia
Timepoint
From the moment of closing the anesthetic (inhaled or intravenous) to the moment of waking the patient if the patient is able to obey instructions and communicate
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Depth of anesthesia
Timepoint
Immediately before and after induction (before starting maintenance dose), while receiving maintenance dose, when discontinuing anesthesia, moment of awakening from anesthesia, end of recovery
Method of measurement
brain function assessment

Intervention groups

1

Description
Intervention group: Group (A) for dexmedetomidine will use an initial bolus dose (0.5 µg / kg) over 10 minutes and a maintenance dose (0.5 µg / kg / h). Propofol will also be used in bolus dose (0.25 mg / kg) and maintenance dose (0.25 mg / kg / h). Propofol ampoule from Dongkook Pharaceutical COtd-company Korea and dexmedetomidine ampoules EXIR manufacturer Iran
Category
Treatment - Drugs

2

Description
Intervention group: Group (B) for dexmedetomidine will use an initial bolus dose (1 µg / kg) over 10 minutes and a maintenance dose (1 µg / kg / h). Propofol will also be used in bolus dose (1.5 mg / kg) and maintenance dose (5 mg / kg / h). In each of these groups, dexmedetomidine and propofol are combined and given to the patient.
Category
Treatment - Drugs

3

Description
Control group: To maintain anesthesia, only N2O 50% anesthetics and MAC isoflurane 1 will be used. N2O gas capsule made in Iran and Bethlehem company and isoflurane solution made in USA and from Piramel Critical care company, INC
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Goli Azzi
Street address
Amir Mazandarani St. Imam Khomeini Hospital
City
Sari
Province
Mazandaran
Postal code
48166-33131
Phone
+98 11 3336 1700
Fax
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Email
Gaezi@mazums.ac.ir
Web page address
https://www.mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saedi
Street address
Joybar intersection of Mazandaran University of Medical Sciences
City
Sari
Province
Mazandaran
Postal code
48157-33971
Phone
+98 11 3325 7230
Fax
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Email
m.saedi@mazums.ac.ir
Web page address

https://www.mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Goli Azzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Amir Mazandarani St. Imam Khomeini Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Goli Azzi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Goli Azzi

Position

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Latest degree

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Web page address

https://www.mazums.ac.ir

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