Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of dexmedetomidine on the prevention of postoperative shivering in patients undergoing eye, ear, throat and nose surgeries

Protocol summary

Study aim

Prophylactic effect of dexmedetomidine on postoperative shivering

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 is performed on 100 patients. Patients are randomly divided into two groups (by lottery method).

Settings and conduct

The location of this study is Razi Hospital in Birjand city. The severity of patients' shivering will be evaluated according to the scoring criteria by the intern. Intern and patients will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria will include having informed consent to enter the study, ASA Class 1 and 2. Exclusion criteria: emergency surgery, patients with ASA 3 and above, drug addiction, history of malignant hyperthermia,Seizures, anaphylaxis, Ischemic heart disease, uncontrolled systemic disease, history of using narcotic drugs; Anti-psychosis, analgesia, alcohol, anti-inflammatory drugs, neuromuscular diseases, thyroid, dysautonomia, pregnancy, obesity.

Intervention groups

In both groups, Ringer's serum is injected before induction of anesthesia. Pre-oxygenation with 5 Lit / min oxygen by anesthesia mask and to induce anesthesia in all patients fentanyl 2 kg / µg and thiopental sodium 5 mg / kg and atracurium 0.5 mg / kg will be used. Maintenance of anesthesia in each group will be performed using propofol 50-150 µg / kg / min. In the intervention group, dexmedetomedine (µg / kg 1) was infused intravenously 10 minutes before extubation.(g / kg µ 1 diluted in 50 cc normal saline) In the control group, 50 cc normal saline is infused intravenously 10 minutes before extubation induction and within 10 minutes. Postoperative shivering is measured and recorded at the beginning of recovery and then every 10 minutes to one hour after surgery.

Main outcome variables

Determining the occurrence of shivering in patients in the intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211009052704N1**
Registration date: **2021-12-04, 1400/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-04, 1400/09/13**
Update count: **0**

Registration date

2021-12-04, 1400/09/13

Registrant information

Name

Sara Bakhtiari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-09, 1400/07/17

Expected recruitment end date

2022-04-06, 1401/01/17

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of dexmedetomidine on the prevention of postoperative shivering in patients undergoing eye, ear, throat and nose surgeries

Public title
Evaluation of the effect of dexmedetomidine on the prevention of postoperative shivering
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to enter the study ASA Class 1 and 2
Exclusion criteria:
Emergency surgery Patients with ASA 3 and above Drug addiction History of Malignant hyperthermia Seizures Anaphylaxis Severe cardiovascular disease Severe kidney, lung, liver disease or any Uncontrolled systemic disease History of taking anti-psychotic drugs, analgesics, narcotics, alcohol, anti-inflammatory drugs Includes both nsaid and corticosteroids Neuromuscular diseases Thyroid disease, Dysautonomy, Obesity (BMI> 30), Pregnancy
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are randomly divided into two groups. Each patient will enter one of the intervention groups randomly before going to the operating room using the color cards that are placed in the envelope and the patient will choose one. For example, if a yellow card is selected, the patient will be in the group receiving dexmedetomidine and if a blue card is selected, the patient will be in the placebo group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The severity of shivering in patients is classified by the intern without knowing the patient group. Patients and the evaluator do not know their group and the drug received (double-blind study).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Ghafari blvd,Birjand town
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Approval date
2021-10-09, 1400/07/17
Ethics committee reference number
IR.BUMS.REC.1400.201

Health conditions studied

1

Description of health condition studied
The effect of dexmedetomidine on the prevention of postoperative shivering in patients undergoing eye, ear, throat and nose surgeries
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Classification of shivering
Timepoint
Classification of shivering immediately after recovery, 10, 20, 30, 40, 50, 60 minutes after surgery
Method of measurement
Zero = lack of muscle tremor / 1 = hair straightening, peripheral cyanosis / 2 = muscle tremor visible in one muscle group / 3 = muscle tremor visible in more than one muscle group / 4 = muscle tremor visible in all muscles of the body by The ward intern will be evaluated without informing the patient group.

Secondary outcomes

1

Description
Comparison of mean systolic and diastolic blood pressure
Timepoint
Comparison of mean systolic and diastolic blood pressure immediately after recovery, 10, 20, 30, 40, 50, 60 minutes after surgery
Method of measurement
Patients' blood pressure is measured with a sphygmomanometer cuff at regular intervals and recorded in prepared tables.

2

Description
Comparison of mean pulse beats
Timepoint
Comparison of mean pulse beats immediately after recovery, 10, 20, 30, 40, 50, 60 minutes after surgery
Method of measurement
Patients' pulse is counted in one minute.

Intervention groups

1

Description
Intervention group: The group of patients is injected with Ringer serum according to the relevant formulas before induction of anesthesia. Pre-oxygenation with 5 Lit / min oxygen is performed by anesthesia mask for all patients. Fentanyl(Darou Pakhsh Pharmaceutical Co./and each vial is 50 micrograms per 10 cc) 2 kg / µg, thiopental sodium(Panpharma Co./500mg) 5 mg / kg and atracurium(Aburaihan Pharmaceutical Co/50 mg per 5 ml) 0.5 mg / kg will be used to induce anesthesia in all patients. Maintenance of anesthesia in each group will be performed using propofol(Fresenius Kabi Co./200 mg per 20 ml) 50-150 µg / kg / min. Temperature All serums were the same and all were supplied from the shared serum storage room. Room temperature between 25-28 degrees and a serum was randomly selected daily to measure the temperature. Environment: Light and temperature were equal and the drugs and liquids were kept in the same rooms in terms of temperature.Monitoring: Routine including ECG, pulse oximetry, NIBP every 10 minutes and capnography were performed for all patients. In the intervention group, dexmedetomedin (1 µg / kg 1) was infused intravenously 10 minutes before extubation. (1 µg / kg diluted in 50 cc normal saline).The vials are provided by Exir Company, Boroujerd, Iran. Each vial is 200 micrograms in 2 ml
Category
Prevention

2

Description
Control group: patients is injected with Ringer serum according to the relevant formulas before induction of anesthesia. Pre-oxygenation with 5 Lit / min oxygen is performed by anesthesia mask for all patients. Fentanyl 2 kg / µg, thiopental sodium 5 mg / kg and atracurium 0.5 mg / kg will be used to induce anesthesia in all patients. Maintenance of anesthesia in each group will be performed using propofol 50-150 µg / kg / min.Temperature All serums were the same and all were supplied from the shared serum storage room. Room temperature between 25-28 degrees and a serum was randomly selected daily to measure the temperature. Environment: Light and temperature were equal and the drugs and liquids were kept in the same rooms in terms of temperature.Monitoring: Routine including ECG, pulse oximetry, NIBP every 10 minutes and capnography were performed for all patients. In the control group, 50 cc of normal saline is infused intravenously 10 minutes before induction of extubation and within 10 minutes. Fentanyl provided by Darou Pakhsh Pharmaceutical Co. and each vial is 50 micrograms per 10 cc. thiopental sodium provided by Panpharma Co./500mg. atracurium provided by Aburaihan Pharmaceutical Co. / 50 mg per 5 ml and propofol provided by Fresenius Kabi Co. 200 mg per 20 ml.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Bibifateme Shakhsimampoor
Street address
Ghafari Blvd, Birjand,South Khorasan Province
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+98 56 3239 5000
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Birjand 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
Birjand University of Medical Sciences

Full name of responsible person
Bibifateme Shakhs Imampoor

Position
Specialist and Assitanat professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Specialist and assitant proffessor

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Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Sara Bakhtiari

Position
Intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
Data related to hemodynamic parameters of the subjects included shivering intensity, heart rate. Patients' systolic and diastolic blood pressure are measured at regular

intervals will be released after the person is unidentified and the effect of the interventions is described in a general article.

When the data will become available and for how long

Accessibility after publishing the article

To whom data/document is available

Published data is accessible to all people working in different fields.

Under which criteria data/document could be used

The data can be used for review and use to develop guidelines and further research on this drug.

From where data/document is obtainable

After completing the study, the documents will be registered in the Pazhoohan.

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

The application will be shared within two working weeks if eligible after review by the project manager.

Comments