Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison the effect of Melatonin and Dexmedetomidine on dose requirements of propofol in induction and maintenance of anesthesia by guidance of BIS in femur fracture surgery

Protocol summary

Study aim
Comparison the effect of Melatonin and Dexmedetomidine on dose requirements of propofol in induction and maintenance of anesthesia by guidance of BIS in femur fracture surgery

Design
Double-blind randomized clinical trial

Settings and conduct
In the dexmedetomidine group, after diluting the drug with normal saline in a 50 ml syringe, 1 µg / kg dexmedetomidine is injected within 15 minutes and after induction of anesthesia, 0.5 µg / kg is injected during surgery. In the melatonin group, 9 mg of melatonin is given sublingually 15 minutes before induction of anesthesia. In the melatonin group, patients receive a normal saline infusion placed on a syringe pump to blind the study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Hypersensitivity to propofol, dexmedetomidine or melatonin, Consumption of opium and psychotropic drugs, Consumption of beta blocker History of liver, kidney and cardiovascular failure, Vascular stroke, Neurological diseases, Diabetes Hypothyroidism, Peripheral or central vascular diseases, History of high blood pressure, History of taking anticonvulsant drugs, Pace maker, Duration of operation more than 180 minutes.

Intervention groups
In the dexmedetomidine group, after diluting the drug with normal saline in a 50 ml syringe, 1 µg / kg dexmedetomidine is injected within 15 minutes and after induction of anesthesia, 0.5 µg / kg is injected during surgery. In the dexmedetomidine group, patients receive a sublingual placebo for blinding 15 minutes before induction of anesthesia. In the melatonin group, 9 mg of melatonin is given sublingually 15 minutes before induction of anesthesia. In the melatonin group, patients receive a normal saline infusion placed on a pump syringe to blind the study.

Main outcome variables
Sedation, anxiety, pain, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N103**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **prospective**

Last update: **2025-05-18, 1404/02/28**
Update count: **1**

Registration date
2020-12-23, 1399/10/03

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-18, 1399/11/30

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Melatonin and Dexmedetomidine on dose requirements of propofol in induction and maintenance of anesthesia by guidance of BIS in femur fracture surgery

Public title

Comparison the effect of Melatonin and Dexmedetomidine on dose requirements of propofol in induction and maintenance of anesthesia by guidance of BIS in femur fracture surgeryon

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 21 and 60 years ASA I ,II BMI 18-30 Elective tympanomastoidectomy

Exclusion criteria:

Hypersensitivity to propofol, dexmedetomidine or melatonin Consumption of opium and psychotropic drugs Consumption of beta blocker History of liver, kidney and cardiovascular failure Vascular stroke Neurological diseases Diabetes Hypothyroidism Peripheral or central vascular diseases History of high blood pressure History of taking anticonvulsant drugs Pace maker Duration of operation more than 180 minutes

Age

From **21 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is from https://www.sealedenvelope.com/. To prevent the last allocation from being revealed, 4, 6 and 8 random blocks will be used to assign individuals to groups. The dark secret envelopes arranged by the study-independent analyzer are returned to the preoperative area by a nurse who is out of the study, and the patient profile sheets are removed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The nurses involved in this study are unaware of the type of intervention. In addition, all patients and authors of this study are unaware of the awakening time, extubation time, variables measured in the recovery room and the order of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2020-06-15, 1399/03/26

Ethics committee reference number

IR.SUMS.MED.REC.1399.172

Health conditions studied

1

Description of health condition studied

Femur Fracture

ICD-10 code

M80.05

ICD-10 code description

Age-related osteoporosis with current pathological fracture, femur

Primary outcomes

1

Description

Sedation

Timepoint

After transfer to the recovery room

Method of measurement

Richmond test

2

Description

Anxiety

Timepoint

The morning of the operation, before entering the operating room. In the recovery room and after full awakening in 30,60,90,120 minutes

Method of measurement

BECk Anxiety Assessment Test

3

Description

Pain

Timepoint

Severity of pain after waking up in the recovery room at 30,60,90,120 minute

Method of measurement

Visual analog Scale

4

Description

Nausea and Vomiting

Timepoint

After transferring patients to the recovery room

Method of measurement

PONV score: 0 = no emetic symptoms, 1 = nausea, 2 = vomiting

Secondary outcomes

1

Description

The duration of the end of surgery until the extubation

Timepoint

The interval from the end of surgery to the removal of the endotracheal tube

Method of measurement

Observation

2

Description

Duration of recovery

Timepoint

Duration of stay in recovery

Method of measurement

Observation

3

Description

The amount of bleeding

Timepoint

At the end of surgery

Method of measurement

Observation

Intervention groups

1

Description

Intervention group:In the dexmedetomidine group, after diluting the drug with normal saline in a 50 ml syringe, 1 µg / kg dexmedetomidine is injected within 15 minutes and after induction of anesthesia, 0.5 µg / kg is injected during surgery.In the dexmedetomidine group, patients receive a sublingual placebo for blinding 15 minutes before induction of anesthesia.

Category

Prevention

2

Description

Intervention group:In the melatonin group, 9 mg of melatonin is given sublingually 15 minutes before induction of anesthesia. In the melatonin group, patients receive a normal saline infusion placed on a syringe pump to blind the study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Reza Jouybar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Reza Jouybar
Position
Cardio_anesthesiologist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Its against our policy.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available