Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of dexmedetomidine in agitation in elective upper limb orthopedic patients candidates for general anesthesia in recovery

Protocol summary

Study aim
Investigating the effect of dexmedetomidine in agitation in elective upper limb orthopedic patients candidates for general anesthesia in recovery

Design
Clinical trial with a control group, parallel groups, double-blind, randomized, phase 3, on 150 patients. Simple randomization and lottery will be used for randomization.

Settings and conduct
This study will be conducted with the aim of investigating the effect of dexmedetomidine in agitation in elective upper limb orthopedic patients candidates for general anesthesia in recovery in Fatemi Hospital in Ardabil. The intervention group will receive dexmedetomidine (Exir Company) with a dose of 0.4 µg per kilogram from induction of anesthesia to extubation, and in the control group, a placebo will be used, similar to the intervention group. Agitation and pain will be evaluated in the recovery. The placebo is similar to the original drug in terms of color, volume, and method of use, and the patients and those who evaluate the outcome will not know about the grouping done, and the study will be double-blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Orthopedic patients candidates for general anesthesia in elective upper surgery. Exclusion criteria: Urgent patients, Patients with uncontrolled disease.

Intervention groups
The intervention group will include orthopedic patients who are candidates for general anesthesia in upper surgeries, and the dexmedetomidine will be evaluated in the level of agitation and pain score during recovery, and the control group will use placebo and the level of agitation and pain score will also be evaluated during recovery.

Main outcome variables
agitation and pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230819059181N1**
Registration date: **2023-09-10, 1402/06/19**
Registration timing: **prospective**

Last update: **2023-09-10, 1402/06/19**
Update count: **0**

Registration date
2023-09-10, 1402/06/19

Registrant information

Name
Ali Abitorabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 45 3372 0209

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of dexmedetomidine in agitation in elective upper limb orthopedic patients candidates for general anesthesia in recovery

Public title

Investigating the effect of dexmedetomidine in restless in orthopedic patients candidates for general anesthesia in recovery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Orthopedic patients candidates for general anesthesia in elective upper surgery

Exclusion criteria:

Urgent patients Patients with uncontrolled disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups receiving dexmedetomidine and placebo. Simple randomization and lottery will be used for randomization. Cards and envelopes are prepared according to the number of the research sample and an equal number of names of groups A and B are recorded on each card. The cards are placed inside the letter envelopes. The lid of the letter envelopes is glued and placed inside a box. At the start of the study, according to the order of entry of the participants, the patient will take one of the envelopes from the box and will be placed in one of the two study groups based on the group written on the card.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in the intervention group will use dexmedetomidine and the control group will use placebo, similar to the intervention group. Patients and doctors who evaluate the outcome will be unaware of the type of drug received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Ave, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2023-08-14, 1402/05/23

Ethics committee reference number

IR.ARUMS.REC.1402.127

Health conditions studied

1

Description of health condition studied

Agitation

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Agitation

Timepoint

15 and 30 minutes after entering recovery

Method of measurement

Ricker sedation-agitation scale

Secondary outcomes

1

Description

Pain

Timepoint

15 and 30 minutes after entering recovery

Method of measurement

Visual Analog Scale

Intervention groups

1

Description

Intervention group: Will receive dexmedetomidine (Exir

Company) with a dose of 0.4 µg per kilogram from induction of anesthesia to extubation.

Category

Prevention

2

Description

Control group: A placebo will be used, similar to the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital in Ardabil

Full name of responsible person

Ali Abitorabi

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Fatemi hospital, Imam Khomeini street, Ardabil

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil 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

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Ali Abitorabi

Position

Resident of ansthesiology

Latest degree

Medical doctor

Other areas of specialty/work

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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