

# 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)

##### Phone

+98 45 3372 0209

##### Email address

atlantis.321@yahoo.com

##### 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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Public title</b>                                                                                                                               | Investigating the effect of dexmedetomidine in restless in orthopedic patients candidates for general anesthesia in recovery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Purpose</b>                                                                                                                                    | Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Inclusion/Exclusion criteria</b>                                                                                                               | <b>Inclusion criteria:</b><br>Orthopedic patients candidates for general anesthesia in elective upper surgery<br><b>Exclusion criteria:</b><br>Urgent patients Patients with uncontrolled disease                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Age</b>                                                                                                                                        | No age limit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Gender</b>                                                                                                                                     | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Phase</b>                                                                                                                                      | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Groups that have been masked</b>                                                                                                               | <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Sample size</b>                                                                                                                                | Target sample size: <b>150</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Randomization (investigator's opinion)</b>                                                                                                     | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Randomization description</b>                                                                                                                  | 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. |
| <b>Blinding (investigator's opinion)</b>                                                                                                          | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Blinding description</b>                                                                                                                       | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Placebo</b>                                                                                                                                    | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Assignment</b>                                                                                                                                 | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Other design features</b>                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Secondary Ids</b>                                                                                                                              | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

|                                                                |
|----------------------------------------------------------------|
| <b>Ethics committees</b>                                       |
| <b><u>1</u></b>                                                |
| <b>Ethics committee</b>                                        |
| <b>Name of ethics committee</b>                                |
| Ethics committee of Ardabil University of Medical Sciences     |
| <b>Street address</b>                                          |
| Ardabil University of Medical Sciences, Daneshgah Ave, Ardabil |
| <b>City</b>                                                    |
| Ardabil                                                        |
| <b>Province</b>                                                |
| Ardabil                                                        |
| <b>Postal code</b>                                             |
| 5618985991                                                     |
| <b>Approval date</b>                                           |
| 2023-08-14, 1402/05/23                                         |
| <b>Ethics committee reference number</b>                       |
| IR.ARUMS.REC.1402.127                                          |
| <b>Health conditions studied</b>                               |
| <b><u>1</u></b>                                                |
| <b>Description of health condition studied</b>                 |
| Agitation                                                      |
| <b>ICD-10 code</b>                                             |
| R45.1                                                          |
| <b>ICD-10 code description</b>                                 |
| Restlessness and agitation                                     |
| <b>Primary outcomes</b>                                        |
| <b><u>1</u></b>                                                |
| <b>Description</b>                                             |
| Agitation                                                      |
| <b>Timepoint</b>                                               |
| 15 and 30 minutes after entering recovery                      |
| <b>Method of measurement</b>                                   |
| Ricker sedation-agitation scale                                |
| <b>Secondary outcomes</b>                                      |
| <b><u>1</u></b>                                                |
| <b>Description</b>                                             |
| Pain                                                           |
| <b>Timepoint</b>                                               |
| 15 and 30 minutes after entering recovery                      |
| <b>Method of measurement</b>                                   |
| Visual Analog Scale                                            |
| <b>Intervention groups</b>                                     |
| <b><u>1</u></b>                                                |
| <b>Description</b>                                             |
| 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

**Street address**

Fatemi hospital, Imam Khomeini street, Ardabil

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5614733775

**Phone**

+98 45 3323 2520

**Email**

fatemi@arums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Farhad Pourfarzi

**Street address**

Vice chancellor for research, Ardabil University of Medical Sciences, Daneshgah Ave, Ardabil

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**Province**

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**Postal code**

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**Phone**

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**Email**

research@arums.ac.ir

**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 anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Basij Square, Ebrahimi alley, plaque 33, unit 6

**City**

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**Province**

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**Postal code**

5615794716

**Phone**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Ali Abitorabi

**Position**

resident of anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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Basij Square, Ebrahimi alley, plaque 33, unit 6

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ardabil University of Medical Sciences  
**Full name of responsible person**  
Ali Abitorabi  
**Position**  
resident of anesthesiology  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Basij Square, Ebrahimi alley, plaque 33, unit 6  
**City**  
Ardabil  
**Province**  
Ardabil  
**Postal code**  
5615794716  
**Phone**

## 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