Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Incidence of Postoperative Delirium in Elderly Patients Over 60 Undergoing Knee Arthroplasty with General Anesthesia Using Propofol or Dexmedetomidine.

Protocol summary

Study aim

Comparison of the Incidence of Postoperative Delirium in Elderly Patients Over 60 Undergoing Knee Arthroplasty with General Anesthesia Using Propofol or Dexmedetomidine

Design

The present study is a double-blind, randomized clinical trial with parallel groups (using block randomization), conducted on a total of 146 patients.

Settings and conduct

In this double-blind, randomized clinical trial, elderly patients over 60 years old scheduled for knee replacement surgery under general anesthesia at Vali Asr Hospital, Arak, will be randomly assigned to two groups (A and B) using block randomization. Blinding will be achieved through syringe labeling of the drugs and patient coding, and the study outcomes will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients scheduled for knee joint replacement surgery under general anesthesia; those who have provided informed consent to participate in the study; surgery duration between 60 to 150 minutes. Exclusion criteria: Presence of systemic or specific diseases such as kidney, liver, cardiovascular diseases, hypertension, diabetes, psychiatric and psychotic disorders, Parkinson's disease, motion sickness, history of chemotherapy, and malignancies; history of substance abuse, chronic analgesic use, allergy to the study drugs, and seasonal allergies.

Intervention groups

Dexmedetomidine group: Patients in this group will receive dexmedetomidine (0.1 mcg/kg per hour) via infusion from the induction of anesthesia until recovery room admission. Propofol group: Patients in this group will receive propofol (100 mcg/kg per minute) via infusion from the induction of anesthesia until recovery room admission.

Main outcome variables

Incidence of delirium, duration of delirium, onset time of delirium, mean arterial pressure, heart rate, and arterial oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N49**
Registration date: **2025-12-30, 1404/10/09**
Registration timing: **prospective**

Last update: **2025-12-30, 1404/10/09**
Update count: **0**

Registration date

2025-12-30, 1404/10/09

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-10, 1404/10/20

Expected recruitment end date

2026-04-09, 1405/01/20

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

Scientific title
Comparison of the Incidence of Postoperative Delirium in Elderly Patients Over 60 Undergoing Knee Arthroplasty with General Anesthesia Using Propofol or Dexmedetomidine.

Public title
Comparison of delirium after knee replacement surgery in elderly patients with propofol and dexmedetomidine.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for knee arthroplasty under general anesthesia Having informed consent to participate in the study Surgical duration between 60 and 150 minutes
Exclusion criteria:
Presence of systemic diseases and history of specific conditions, including renal, hepatic, and cardiovascular diseases, hypertension, diabetes, hematological and vascular diseases, psychotic and mental disorders, Parkinson’s disease, motion sickness, a history of chemotherapy, and malignancies. History of substance use and drug allergies, including absence of opioid use, chronic use of analgesics, hypersensitivity to the medications under study, and seasonal allergies.
Age
From **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **146**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to two intervention groups based on their order of entry and according to a randomization sequence that will be generated in advance. This sequence will be unpredictable, and the allocation will be entirely random. Block randomization with blocks of 4 will be used for sample allocation. Using software to generate random numbers in a block design, a randomization sequence will be created according to the required sample size for the two groups. Initially, all possible combinations of the letters A and B within the 4-item blocks will be arranged. Then, one block is randomly selected, and its arrangement will be used for allocating participants. Afterward, this block is placed in the main container, and another block is selected. All these steps will be performed using software called Sealed Envelope. With this method, concealment will also be maintained. The concept of concealment means that the allocation of participants to groups is unpredictable. In practice, the researcher will not be able to predict which group the next participant will be assigned to.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind trial. None of the patients will be aware of the type of drug they are receiving. These drugs will be administered by the anesthesiologist, with each drug drawn into a separate syringe. The syringes and the extension tubes connecting the syringes to the angiocatheter will be covered with foil, so the contents will remain unknown. As a result, the intern responsible for recording outcomes will not know the patient group assignment and will assess the patients based on their file numbers, then provide the collected data to the attending physician.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2025-10-19, 1404/07/27
Ethics committee reference number
IR.ARAKMU.REC.1404.259

Health conditions studied

1

Description of health condition studied
Postoperative Delirium
ICD-10 code
F05
ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description
Occurrence of delirium
Timepoint
After surgery
Method of measurement
Confusion Assessment Method

2

Description
Duration of delirium
Timepoint
After surgery
Method of measurement
By the Watch

3

Description
Time of onset of delirium
Timepoint
The first, second, and third days after surgery
Method of measurement
Patient file

4

Description
Duration until discharge from the recovery unit
Timepoint
After surgical recovery
Method of measurement
Modified Aldrete Score

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
At the beginning of surgery and every 15 minutes during the operation, throughout the recovery period, and at 2, 4, and 6 hours after surgery.
Method of measurement
NIBP monitoring device

2

Description
Heart rate
Timepoint
At the beginning of surgery and every 15 minutes during the operation, throughout the recovery period, and at 2, 4, and 6 hours after surgery.
Method of measurement
Cardiac monitoring device

3

Description
Arterial blood oxygen saturation
Timepoint
At the beginning of surgery and every 15 minutes during the operation, throughout the recovery period, and at 2, 4, and 6 hours after surgery.
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Dexmedetomidine group: Patients in this group will receive dexmedetomidine (0.1 µg/kg/h) as a continuous infusion from the time of anesthesia induction until admission to the recovery room.
Category
Treatment - Drugs

2

Description
Propofol group: Patients in this group will receive propofol (100 µg/kg/min) as a continuous infusion from the time of anesthesia induction until admission to the recovery room .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Valiasr Hospital
Full name of responsible person
Dr. Hesamuddin Modir
Street address
Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran
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3814957558
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr. Alireza Susanabadi
Position
Associate 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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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Bagher Jamshidpour
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Student
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Other areas of specialty/work
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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

No - There is not 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

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

The access period will start on 2026/04/19, and continue until 2029/04/18 for a duration of three years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

University researchers and university professors can request Dr. Ahmadreza Behrouzi to use the data after contacting the relevant professor via message or email. Dr. Hesamuddin Modiri: Phone: 09183615107 Email: modir.he@gmail.com, Address: Valiasr Hospital, Arak, Vice-Chancellor of Hospital Education.

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

Letter writing should be done with professors and universities.

Comments