Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Incidence and Severity of Postoperative Delirium and Agitation After Shoulder Surgery: Comparison Between Regional Anesthesia Alone and Combined Regional–General Anesthesia

Protocol summary

Study aim

To compare the incidence and severity of postoperative delirium and emergence agitation in patients undergoing shoulder surgery. The study will evaluate outcomes between regional anesthesia alone versus combined regional plus general anesthesia.

Design

Single-center, two-arm, parallel-group randomized controlled trial with concealed block randomization and blinded outcome assessment (n=80).

Settings and conduct

The study will be done at Akhtar Hospital. The data analyzers will be blinded to the groupings

Participants/Inclusion and exclusion criteria

Inclusion criteria Adult patients scheduled for elective shoulder surgery ASA physical status I–III Candidate for regional anesthesia (interscalene block) Ability to provide informed consent Exclusion criteria Pre-existing cognitive impairment or dementia History of delirium, psychosis, or major psychiatric illness Chronic use of antipsychotics or sedative-hypnotics Alcohol or substance abuse Severe hearing/communication problems preventing assessment Contraindications to regional anesthesia (infection at site, coagulopathy, allergy to local anesthetics) Emergency surgery Refusal to participate

Intervention groups

Group A: Regional anesthesia alone Ultrasound-guided interscalene brachial plexus block Sedation only if required (standardized minimal sedation protocol) Group B: Combined regional + general anesthesia Ultrasound-guided interscalene brachial plexus block Standard general anesthesia (induction + airway management + maintenance)

Main outcome variables

Incidence of postoperative delirium (within PACU and first 24 hours after surgery) Severity of postoperative delirium (PACU and within 24 hours postoperatively) Incidence of emergence agitation (during emergence and in PACU) Severity of emergence agitation (peak agitation score during emergence and PACU)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260203068755N1**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

Registration date

2026-05-13, 1405/02/23

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-14, 1404/11/25

Expected recruitment end date

2028-02-14, 1406/11/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Incidence and Severity of Postoperative Delirium and Agitation After Shoulder Surgery: Comparison Between Regional Anesthesia Alone and Combined Regional–General Anesthesia

Public title
Incidence and Severity of Postoperative Delirium and Agitation After Shoulder Surgery: Comparison Between Regional Anesthesia Alone and Combined Regional–General Anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients scheduled for elective shoulder surgery ASA physical status I–III Candidate for regional anesthesia (interscalene block) Ability to provide informed consent
Exclusion criteria:
Pre-existing cognitive impairment or dementia History of delirium, psychosis, or major psychiatric illness Chronic use of antipsychotics or sedative-hypnotics Alcohol or substance abuse Severe hearing/communication problems preventing assessment Contraindications to regional anesthesia (infection at site, coagulopathy, allergy to local anesthetics) Emergency surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
1) Allocation ratio Eligible participants will be allocated in a 1:1 ratio into two parallel groups: Group A: Regional anesthesia alone (RA) Group B: Combined regional + general anesthesia (RA+GA) 2) Sequence generation (how the random list is created) An independent person (e.g., a statistician or a researcher not involved in anesthesia delivery or outcome assessment) will generate the randomization sequence. A computer-generated random sequence will be created using software such as Randomization.com, SPSS, or Microsoft Excel. To ensure balance between the groups during recruitment, block randomization will be used. 3) Block randomization (to keep groups balanced) Variable block sizes will be applied to reduce predictability (e.g., block sizes of 4 and 6, randomly mixed). Within each block, equal numbers of participants will be assigned to each group, but the order will be randomized. Example: In a block of 4, 2 patients will be allocated to RA and 2 to RA+GA, but in random order. 4) Allocation concealment (preventing prediction) To ensure that no one can predict the next assignment, allocation concealment will be performed using the standard SNOSE method: Sealed, Opaque, Sequentially Numbered Envelopes (SNOSE) Envelopes will be opaque, light-proof, sealed, and sequentially numbered (001 to 060). Each envelope will contain a paper indicating the assigned group (RA or RA+GA). Envelopes will be prepared and sealed by an independent researcher. The envelopes will be stored securely until use. 5) Implementation (when and who opens the envelope) After confirming eligibility and obtaining written informed consent, each participant will receive a study ID (e.g., 001, 002, …, 060). The anesthesia provider (who is not blinded) will open the corresponding envelope immediately before anesthesia induction. The group allocation will be recorded in a confidential allocation log. 6) Documentation and quality control The master randomization list will remain with the independent statistician and will not be accessible to assessors. Used envelopes will be retained for auditing and verification. Any protocol deviations will be documented. 7) Cross-over management and analysis plan If a participant allocated to RA alone requires conversion to general anesthesia for clinical reasons: General anesthesia will be administered as needed (patient safety is the priority). The case will be recorded as a protocol deviation/crossover. The participant will remain in the original allocated group for the primary analysis based on the Intention-To-Treat (ITT) principle. A secondary Per-Protocol (PP) analysis may also be performed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Because the interventions are anesthesia techniques, full blinding of the anesthesia provider is not possible. However, this study will be implemented as a practical double-blind trial, meaning: Participants will be blinded Postoperative outcome assessors will be blinded Data analysts/statisticians will be blinded The anesthesia provider delivering anesthesia will not be blinded 1) Participant blinding Participants will not be informed about their group assignment. To maintain participant blinding: Both groups will undergo similar preoperative preparation and operating room workflow. All patients will receive an ultrasound-guided interscalene block. To minimize the patient’s ability to identify the anesthetic technique, standardized light sedation may be used when clinically appropriate. The informed consent will state that the patient will receive one of two standard anesthesia approaches. 2) Outcome assessor blinding Postoperative delirium and agitation will be assessed by trained personnel (e.g., PACU nurse/research assistant) who: Are not involved in anesthesia delivery Do not have access to anesthesia records Will assess outcomes only using the participant study ID Assessment tools may

include: Confusion Assessment Method (CAM) / CAM-ICU Richmond Agitation-Sedation Scale (RASS) or Sedation-Agitation Scale 3) Data analyst blinding All collected data will be entered into the database using coded group labels (Group A and Group B). The statistician will receive the dataset without knowing which group corresponds to RA or RA+GA. Group identity will be revealed only after completion of the primary statistical analysis. 4) Standardization of perioperative care to maintain blinding To reduce the chance of group disclosure: Postoperative pain control, antiemetic use, and sedation protocols will be standardized across groups. The anesthesia record will be kept separate from the outcome assessment forms. PACU and ward staff will be instructed not to discuss anesthesia type in the presence of the blinded assessor. 5) Prevention and documentation of unblinding Assessors will not be allowed to review the anesthesia chart. If unblinding is suspected (e.g., the assessor guesses the group), this will be recorded in a separate form as “assessor guess of allocation” to evaluate blinding quality. 6) Emergency unblinding Emergency unblinding will be permitted only if knowledge of the anesthetic technique is clinically essential for patient management. The reason for unblinding will be documented. The date/time and personnel involved will be recorded. The participant will still remain in the ITT analysis.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address

Shahid Chamran Highway- Evin- next to Taleghani Hospital- Medical School- third floor

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2026-01-31, 1404/11/11

Ethics committee reference number

IR.SBMU.MSP.REC.1404.733

Health conditions studied

1

Description of health condition studied

Shoulder surgery

ICD-10 code

S40-S49

ICD-10 code description

Injuries to the shoulder and upper arm

Primary outcomes

1

Description

• Incidence of postoperative delirium (PACU and within the first 24 hours after surgery) • Severity of postoperative delirium (PACU and within the first 24 hours after surgery) • Incidence of emergence agitation (during emergence and in PACU) • Severity of emergence agitation (peak agitation score during emergence and in PACU)

Timepoint

: Primary outcomes will be assessed at the following timepoints:1- Baseline (preoperative assessment, before anesthesia/intervention)2- Immediately after emergence from anesthesia (at awakening/extubation)3- During PACU stay (within the first 60 minutes postoperatively)4- 6 hours after surgery5- 24 hours after surgery

Method of measurement

Measurement of Primary Outcome Variables1) Postoperative delirium (incidence and severity)• Tool (incidence): Confusion Assessment Method (CAM) for ward assessments; CAM-ICU if assessed in PACU/ICU-style setting for nonverbal or heavily sedated patients.• How measured: A trained blinded assessor performs CAM/CAM-ICU at each scheduled timepoint; delirium is recorded as present/absent based on the tool’s algorithm.• Tool (severity): CAM-S (Confusion Assessment Method–Severity score) or a validated delirium severity scale available at your center (e.g., DRS-R-98 if used locally).• How measured: Severity is documented as the total score at each timepoint; the highest score within 24 hours can be used as the main severity metric.2) Emergence agitation (incidence and severity)• Tool: Richmond Agitation–Sedation Scale (RASS) (or Riker Sedation–Agitation Scale (SAS) if that is your institutional standard).• How measured: The blinded assessor rates the patient during emergence and in PACU.o Incidence: agitation defined as RASS ≥ +2 (or SAS ≥ 5, if SAS is used).o Severity: recorded as the peak agitation score (maximum RASS/SAS value) during emergence and PACU observation.Standardization and blinding• All assessments will be performed by trained staff blinded to group allocation, using standardized instructions, and recorded on a predefined case report form.If you tell me which scales your hospital already uses (CAM vs CAM-ICU only, and RASS vs SAS), I can lock it to one exact tool to match your protocol perfectly.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Combined regional–general anesthesia. Ultrasound-guided interscalene brachial plexus block will be performed preoperatively followed by standardized general anesthesia (IV induction, airway management, and maintenance with inhalational anesthetic) in addition to the regional block.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar hospital
Full name of responsible person
Shayan Kamalfar
Street address
Akhtar Hospital - Azar Dead End - Sharifi Manesh Street - In front of Qaitariya metro - Shariati Avenue - Tehran
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Sponsors / Funding sources

1

Sponsor
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shayan Kamalfar
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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

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 regarding anesthesia and outcomes measurements will be available.

When the data will become available and for how long

After data collection completion

To whom data/document is available

Other researchers

Under which criteria data/document could be used

belonging to academic institution

From where data/document is obtainable

researcher's personal email shayankamalfar@sbmu.ac.ir

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

requesting by email

Comments