Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of preventive analgesia with methylprednisolone plus gabapentin versus methylprednisolone alone in elderly patients undergoing total knee arthroplasty

Protocol summary

Study aim
The comparison of preventive analgesia with methylprednisolone plus gabapentin versus methylprednisolone alone in elderly patients undergoing total knee arthroplasty

Design
This clinical trial will be conducted with two parallel groups: one receiving methylprednisolone in combination with gabapentin and the other receiving methylprednisolone without gabapentin, with no control group. The study will follow a double-blind, randomized design in phase 2–3 and will enroll 140 patients. Randomization will be performed using permuted blocks of four.

Settings and conduct
Study site: Orthopedic and Anesthesia Departments of Imam Reza Hospital, Tabriz, Islamic Republic of Iran; study population: patients over 60 years of age scheduled for elective unilateral total knee arthroplasty; type of blinding: double-blind; blinding procedure: both patients and outcome assessors were unaware of group assignments, and medications were prepared as identical oral capsules and injectable ampoules coded as A and B by an independent pharmacist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged over 60 years; physical status class I or II according to the American Society of Anesthesiologists (ASA) classification; candidates for elective unilateral total knee arthroplasty; receiving preemptive analgesia with methylprednisolone beta alone or combined with gabapentin. Exclusion criteria: any contraindication for spinal anesthesia; previous use of corticosteroid medications.

Intervention groups
Intervention group (Group A): patients in this group will receive methylprednisolone combined with gabapentin as preemptive analgesia before total knee arthroplasty.
Control group (Group B): patients in this group will receive methylprednisolone alone, without gabapentin, as preemptive analgesia prior to surgery.

Main outcome variables
Postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N64**
Registration date: **2025-10-20, 1404/07/28**
Registration timing: **retrospective**

Last update: **2025-10-20, 1404/07/28**
Update count: **0**

Registration date
2025-10-20, 1404/07/28

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 7054

Email address
khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-23, 1403/04/03

Expected recruitment end date
2025-06-24, 1404/04/03

Actual recruitment start date
2024-06-23, 1403/04/03
Actual recruitment end date
2025-06-24, 1404/04/03
Trial completion date
2025-06-24, 1404/04/03

Scientific title
The comparison of preventive analgesia with methylprednisolone plus gabapentin versus methylprednisolone alone in elderly patients undergoing total knee arthroplasty

Public title
Preventive analgesia with methylprednisolone beta with and without gabapentin in elderly patients undergoing total knee arthroplasty
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Over 60 years of age ASA class I or II Candidate for elective unilateral total knee arthroplasty
Exclusion criteria:
Patients with any contraindication to spinal anesthesia Prior use of corticosteroid medications
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **140**
Actual sample size reached: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, with a sample size of 140 participants, patients will be allocated into two groups using the block permutation randomization method. Each block will contain four patients, including all possible combinations: Block 1 – BBAA, Block 2 – AABB, Block 3 – ABAB, Block 4 – BABA, Block 5 – ABBA, and Block 6 – BAAB. For 140 participants, 35 blocks will be used, and block numbers from 1 to 6 will be randomly selected with the aid of Random Allocation Software. For example, if Block 6 is chosen as the first block and Block 2 as the second, the allocation sequence will be BAABAABB, assigning individuals to either the methylprednisolone plus gabapentin group (A) or the methylprednisolone without gabapentin group (B). To ensure allocation concealment, the randomization list will be prepared by an independent researcher who will not be involved in patient recruitment or assessment. The list will be numbered and sealed inside opaque, sequentially numbered, light-impermeable envelopes. The principal investigator will open the envelopes in numerical order only after each participant has been enrolled and assigned a code, thereby preventing any prediction of group assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind study, both patients and outcome assessors were kept unaware of group assignments by preparing the two medications in identical capsules with the same shape, size, color, and taste, manufactured and packaged by an independent pharmacist. Each capsule was labeled only with codes “A” and “B,” determined by a randomization table generated by an independent investigator. Thus, neither the patients, nor data analysts were informed of the assigned intervention, and the coding list remained confidential with the pharmacist until the completion of statistical analysis to ensure full blinding integrity.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Imam Reza Hospital, Azadi Avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631
Approval date
2024-06-23, 1403/04/03
Ethics committee reference number
IR.TBZMED.REC.1403.249

Health conditions studied

1

Description of health condition studied
Postoperative pain
ICD-10 code
G89.11
ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Postoperative pain
Timepoint
Every two hours for 24 hours
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Thirty minutes before transfer to the operating room, patients will receive a 300-mg oral gabapentin tablet with 50 mL of water, followed by intravenous administration of a 125-mg methylprednisolone ampule. Pain intensity will be assessed using the Visual Analog Scale (VAS) over a 24-hour period at two-hour intervals.
Category
Prevention

2

Description
Intervention group 2: Thirty minutes before transfer to the operating room, patients will receive an oral placebo tablet identical in color, size, and shape to the gabapentin tablet, along with 50 mL of water, followed by intravenous administration of a 125-mg methylprednisolone ampule. Pain intensity will be assessed using the Visual Analog Scale (VAS) over a 24-hour period at two-hour intervals.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Mahdi Nazari
Street address
Imam Reza Hospital, Azadi Avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5981764863
Phone
+98 41 3535 3696
Email
j.kHOOBAN@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
Imam Reza Hospital, Azadi Avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631
Phone
+98 41 3335 7310
Email
Ajouyban@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Imam Reza Hospital, Azadi Avenue
City
Tabriz
Province

East Azarbaijan

Postal code
5981764863

Phone
+98 41 3334 7054

Fax

Email
Khanbabayimehdi69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Imam Reza Hospital, Azadi Avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5981764863

Phone
+98 41 3334 7054

Fax

Email
Khanbabayimehdi69@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Imam Reza Hospital, Azadi Avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5981764863

Phone
+98 41 3334 7054

Fax

Email
Khanbabayimehdi69@gmail.com

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
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available