Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Low-Dose Ondansetron Combined with Dexamethasone for the Prevention of Postoperative Nausea and Vomiting Following Total Knee Arthroplasty

Protocol summary

Study aim

Efficacy of Low-Dose Ondansetron Combined with Dexamethasone for the Prevention of Postoperative Nausea and Vomiting Following Total Knee Arthroplasty

Design

This randomized, double-blind, parallel-group phase II/III clinical trial will enroll 110 patients assigned 110 patients assigned to one of two groupsansetron plus dexamethasone or placebo plus dexamethasone, administered by injection before induction of anesthesia. No separate control group will be included. Randomization will be performed using permuted blocks of four.

Settings and conduct

In this randomized, double-blind trial on total knee arthroplasty patients at Imam Reza Hospital (Tabriz), participants will receive IV dexamethasone (0.2 mg/kg) combined with either ondansetron (0.05 mg/kg) or saline placebo 10 minutes pre-induction; patients and outcome assessors will remain blinded using identical, code-labeled syringes prepared independently.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Candidates for total knee arthroplasty under general anesthesia Patients with ASA Physical Status I and II Exclusion Criteria: Patients with known hypersensitivity to the study medications Patients with a history of postoperative nausea and vomiting

Intervention groups

In this study, conducted at Imam Reza Hospital in Tabriz, patients undergoing total knee arthroplasty will be assigned to two groups: Group A will receive low-dose ondansetron combined with dexamethasone, and Group B will receive dexamethasone plus a placebo, prior to the induction of anesthesia. The administration of these medications will be performed by the attending anesthesiologist.

Main outcome variables

Postoperative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N87**
Registration date: **2026-09-20, 1405/06/29**
Registration timing: **prospective**

Last update: **2026-09-20, 1405/06/29**
Update count: **0**

Registration date

2026-09-20, 1405/06/29

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

recruiting

Funding source

Expected recruitment start date

2026-10-06, 1405/07/14

Expected recruitment end date

2026-12-20, 1405/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Efficacy of Low-Dose Ondansetron Combined with Dexamethasone for the Prevention of Postoperative Nausea and Vomiting Following Total Knee Arthroplasty

Public title
Effect of Low-Dose Ondansetron Plus Dexamethasone on Postoperative Nausea and Vomiting in Total Knee Arthroplasty

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
American Society of Anesthesiologists (ASA) Physical Status Classification I and II Patients undergoing total knee arthroplasty under general anesthesia

Exclusion criteria:
Patients with known hypersensitivity to the study medications Patients with a history of postoperative nausea and vomiting (PONV)

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, with a sample size of 110 , participants will be assigned to three groups using permuted block randomization. A block size of four will be employed, utilizing all possible combinations, including: Block 1 (BBAA), Block 2 (AABB), Block 3 (ABAB), Block 4 (BABA), Block 5 (ABBA), and Block 6 (BAAB). To accommodate 110 participants, 28 blocks will be generated using Random Allocation Software, with blocks randomly selected from numbers 1 to 6. For instance, if block 6 and block 2 are selected sequentially, the allocation sequence will be BAABAABB, assigning individuals to Intervention Group (A)and the Control Group (B). To ensure allocation concealment, the randomization list will be prepared and numbered by an independent researcher who is not involved in patient recruitment or assessment. The assignments will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). The study investigator will open the envelopes in numerical order only after a patient has been formally enrolled and their code has been recorded, ensuring that the allocation sequence remains unpredictable.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, to ensure proper patient blinding, the medications for groups A and B will be prepared in identical appearance, color, packaging, and administration method, making them indistinguishable to participants. Each medication will be labeled with a unique code (A or B), known only to an independent researcher who is not involved in patient recruitment or evaluation. The envelopes containing the coded medication will be provided to the study investigator in sequential order, without any indication of treatment type. Consequently, both patients and the investigator will remain unaware of group allocation, thus maintaining a practical and effective double-blind design throughout the trial.

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 Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2026-06-07, 1405/03/17

Ethics committee reference number
IR.TBZMED.REC.1405.180

Health conditions studied

1

Description of health condition studied
Postoperative nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Postoperative nausea and vomiting

Timepoint
For 24 hours post-anesthesia at time intervals of 1, 2, 4, 6, 12, 18, and 24 hours.
Method of measurement
To observe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, ondansetron (0.05 mg/kg) combined with dexamethasone (0.2 mg/kg) will be administered intravenously over 10 minutes, three minutes prior to the induction of general anesthesia. Patients will be monitored for 24 hours post-anesthesia at time intervals of 1, 2, 4, 6, 12, 18, and 24 hours.All medications will be supplied by Abidi Pharmaceuticals.
Category
Treatment - Drugs

2

Description
Control group: In the control group, a placebo combined with dexamethasone (0.2 mg/kg) will be administered intravenously over 10 minutes, three minutes prior to the induction of general anesthesia. Patients will be monitored for 24 hours post-anesthesia at time intervals of 1, 2, 4, 6, 12, 18, and 24 hours.All medications will be supplied by Abidi Pharmaceuticals.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Abbasali Dorosti
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
6165665631
Phone
+98 21 3335 5921
Email
mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosrow Adibkia
Street address
Imam Reza Hospital, Azadi Ave
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 Ave
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 Ave

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 Ave

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

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