Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of diclofenac potassium and oral paracetamol on postoperative pain of elective inguinal hernia repair surgery

Protocol summary

Study aim

To determine the effects of oral diclofenac potassium and paracetamol on postoperative pain control following elective inguinal hernia repair surgery

Design

A randomized, double-blind, active-controlled, parallel-group, phase 3 clinical trial on 34 patients. Randomization was performed using block randomization with variable block sizes (blocks of 4 and 6) generated by Random Allocation Software. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE).

Settings and conduct

In this double-blind trial at Imam Khomeini Hospital (Urmia), 34 hernia repair patients are randomized to receive identical capsules of diclofenac potassium (75 mg) or paracetamol (1 g) 60 min preoperatively. Pain is assessed via NRS at 6, 12, and 24 h; patients, assessors, and clinical staff are fully blinded.

Participants/Inclusion and exclusion criteria

Inclusion: Patients aged >18 years undergoing elective inguinal hernia repair at Imam Khomeini Hospital (2024).Exclusion: Drug allergy; analgesic use within 24 hours pre-surgery; history of GI bleeding; asthma; substance/alcohol abuse; comorbidities (anemia, DM, HTN, arthritis); renal impairment (creatinine >1.6 mg/dL); follow-up failure or major complications.

Intervention groups

Patients are allocated into two groups: (1) Intervention group: receiving an oral dose of 75 mg diclofenac potassium 60 minutes preoperatively; and (2) Active control group: receiving an oral dose of 1 g paracetamol 60 minutes preoperatively. General anesthesia protocols and postoperative rescue analgesia are identical in both arms.

Main outcome variables

Postoperative pain intensity (static and dynamic) via NRS at 6, 12, and 24 h; Total rescue analgesic consumption within 24 h; Time to first analgesic request; Adverse drug reactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056613N9**
Registration date: **2026-08-20, 1405/05/29**
Registration timing: **prospective**

Last update: **2026-08-20, 1405/05/29**
Update count: **0**

Registration date

2026-08-20, 1405/05/29

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of diclofenac potassium and oral paracetamol on postoperative pain of elective inguinal hernia repair surgery

Public title
Comparison of the analgesic effects of diclofenac and paracetamol on post-hernia surgery pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult patients (≥18 years) Patients undergoing elective inguinal surgery

Exclusion criteria:
Concomitant medical or psychiatric conditions that could prevent completion of follow-up. History of upper gastrointestinal bleeding related to prior treatment with NSAIDs. Underlying comorbidities (anemia, DM, HTN, arthritis) Moderate or severe renal patients" and "Creatinine > 1.6" Known asthmatic patients. History of alcohol consumption, opioid use, or use of other illicit drugs. Use of NSAIDs or paracetamol within 24 hours before surgery. Participants with known allergy to the study drugs. (Any) intervention required in the event of complications.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
In this randomized, double-blind clinical trial, eligible patients scheduled for elective inguinal hernia repair are allocated to either the oral diclofenac potassium (75 mg) or oral paracetamol (1 g) group using block randomization with permuted blocks of varying sizes. The random allocation sequence is generated using computer-generated random numbers by an independent biostatistician not involved in clinical care. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) are used. Each envelope is opened only on the morning of surgery (60 minutes preoperatively) by a designated nurse after baseline evaluations and written informed consent are completed. Both the patients and the outcome assessors remain fully blinded to group assignments throughout the intervention and follow-up periods.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed and conducted as a double-blind randomized clinical trial. Patients and outcome assessors (who evaluate NRS pain scores, total analgesic consumption, and adverse effects) are blinded to the assigned treatment groups (oral diclofenac potassium vs. oral paracetamol); study medications are coded and prepared in identical, sequentially numbered, opaque packages by an independent researcher not involved in clinical care. Furthermore, healthcare staff administering routine care and rescue analgesia are unaware of group allocations, and randomization codes will remain concealed until data collection and statistical analyses are fully completed.

Placebo
Not used

Assignment
Parallel

Other design features
Specific methodological features of this trial include the strict standardization of the general anesthesia protocol across all study groups, without the use of regional nerve blocks or neuraxial anesthesia, to eliminate confounding effects on postoperative pain. Additionally, postoperative pain intensity is evaluated both at rest (static NRS) and during voluntary coughing (dynamic NRS) to ensure a comprehensive assessment of analgesic efficacy during physical movement. Furthermore, the Numerical Rating Scale (NRS) was selected over the Visual Analogue Scale (VAS) due to its documented higher compliance rates, superior responsiveness, and ease of use in a mixed-age adult population.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research of Imam Khomeini Medical Education Center of Urmia University of Medica

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Emam Khomeini University Hospital, Ershad Ave., Modarres Blvd.

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Approval date
2025-07-30, 1404/05/08

Ethics committee reference number
IR.UMSU.HIMAM.REC.1404.035

Health conditions studied

1

Description of health condition studied
Inguinal Hernia
ICD-10 code
K40
ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Postoperative Acute Pain Intensity
Timepoint
at 6, 12, and 24 hours postoperatively
Method of measurement
using the Numeric Rating Scale (NRS) on an 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diclofenac Potassium Group Patients in this group receive a single oral dose of 75 mg diclofenac potassium in an opaque capsule with 30 mL of water, administered 60 minutes prior to surgery (preemptively). Capsules are identical in shape, size, color, weight, and packaging to the active control group.
Category
Treatment - Drugs

2

Description
Intervention group: Active Control Group (Paracetamol)Patients in this group receive a single oral dose of 1 g (1000 mg) paracetamol in an opaque capsule with 30 mL of water, administered 60 minutes prior to surgery (preemptively). Capsules are identical in appearance, size, color, weight, and coding to the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Urmia
Full name of responsible person
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Sponsors / Funding sources

1

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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Ali Akbar Nasiri

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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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