Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Effectiveness of Oral Duloxetine on Reducing Postoperative Pain and Anxiety Following Open Inguinal Hernia Repair: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial.

Protocol summary

Study aim

Investigating the effectiveness of oral duloxetine on reducing pain after inguinal hernia surgery in patients admitted to Ashair Hospital in Khorramabad city

Design

A prospective, randomized, double-blind, placebo-controlled clinical trial conducted on 100 patients with a 1:1 allocation ratio utilizing block randomization.

Settings and conduct

This study will be conducted at the Clinical Research Development Unit of Shohadaye Ashair Hospital in Khorramabad. Eligible patients are randomly assigned to either the Duloxetine or Placebo group using computer-generated sequences and concealed opaque envelopes. Standardized surgical techniques (Lichtenstein tension-free mesh repair) and anesthesia protocols (Propofol, Remifentanil, Sevoflurane) will be applied uniformly. Clinical outcomes will be recorded by blinded assessors.

Participants/Inclusion and exclusion criteria

The study includes 100 male patients aged 21-60 years who are candidates for open primary inguinal hernia repair and classified as ASA I-II. Patients with BMI ≥ 40, bilateral or recurrent hernias, chronic pain conditions, or chronic use of analgesics and antidepressants are excluded.

Intervention groups

Intervention Group: Receives oral Duloxetine (60mg 2 hours pre-operation, followed by 60mg daily for 2 days). Control Group: Receives a matching placebo capsule at identical time intervals.

Main outcome variables

Pain intensity (VAS AUC), rebound tenderness, quality of recovery (QoR-15), sleep quality (PSQI), post-operative anxiety (STAI), quality of life (EuraHS-QoL, EQ-5D-5L), patient satisfaction, cumulative post-operative analgesic consumption.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230410057871N14**
Registration date: **2026-06-27, 1405/04/06**
Registration timing: **prospective**

Last update: **2026-06-27, 1405/04/06**
Update count: **0**

Registration date

2026-06-27, 1405/04/06

Registrant information

Name

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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

2027-09-23, 1406/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the Effectiveness of Oral Duloxetine on Reducing Postoperative Pain and Anxiety Following Open Inguinal Hernia Repair: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial.

Public title
The Effect of Duloxetine on Pain and Anxiety After Hernia Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male patients aged 21 to 60 years. Candidates for primary open inguinal hernia repair. Fully conscious and capable of understanding the study and completing questionnaires. Absence of chronic pain conditions (e.g., arthritis, fibromyalgia, peripheral neuropathy).

Exclusion criteria:
Chronic use of antidepressants, anxiolytics, or analgesics. History of recurrent inguinal hernia or previous surgery on the ipsilateral side. Bilateral hernia or symptomatic contralateral hernia. Body Mass Index (BMI) ≥ 40 kg/m². American Society of Anesthesiologists (ASA) physical status > III. History of allergy or intolerance to duloxetine or related medications. Psychiatric disorders or language barriers interfering with follow-up or questionnaire completion. Unwillingness to participate or withdrawal at any stage.

Age
From **21 years** old to **60 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be utilized to allocate 100 eligible patients into two equal groups (intervention and control) with a 1:1 ratio. The random sequence will be generated using a computer-based random number generator (Randomization.com). Allocation concealment will be strictly maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent third party unaware of the study group assignments.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind study. Both the active medication (duloxetine) and placebo will be completely identical in appearance, packaging, and administration timing. Patients, operating room staff, clinical care providers, and outcome assessors will remain fully blinded to the group allocations throughout the study. The pharmacist dispensing the medications will not be involved in patient evaluation or data collection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Lorestan, Khorramabad, Moallem Street

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Province
Lorestan

Postal code
6813833946

Approval date
2026-06-02, 1405/03/12

Ethics committee reference number
IR.LUMS.REC.1405.141

Health conditions studied

1

Description of health condition studied
Ashayer Hospital, Khorramabad

ICD-10 code
G89.28

ICD-10 code description
Other chronic postprocedural pain

Primary outcomes

1

Description
Postoperative pain intensity assessed using the Area Under the Curve (AUC) of Visual Analogue Scale (VAS) scores

Timepoint
Evaluated pre-operatively, immediately post-operation, and subsequently at 2 weeks, 1 month, 3 months, and 6 months post-surgery.

Method of measurement
100-mm Visual Analogue Scale (VAS) questionnaire (0 = no pain, 100 = worst possible pain).

Secondary outcomes

1

Description
Incidence and duration of rebound tenderness (acute pain upon release of palpation).
Timepoint
Post-operative period following the resolution of sensory block.
Method of measurement
Clinical physical examination.

2

Description
Quality of post-operative recovery.
Timepoint
Post-operative phase.
Method of measurement
QoR-15 Questionnaire.

3

Description
Quality of sleep.
Timepoint
Post-operative phase.
Method of measurement
Pittsburgh Sleep Quality Index (PSQI).

4

Description
Post-operative anxiety levels.
Timepoint
Post-operative phase.
Method of measurement
State-Trait Anxiety Inventory (STAI).

5

Description
Patient Quality of Life.
Timepoint
Baseline, and at 1.5, 3, 6, and 12 months post-operation.
Method of measurement
EuraHS-QoL or EQ-5D-5L questionnaires

6

Description
Patient satisfaction.
Timepoint
3 and 12 months post-treatment.
Method of measurement
11-point numerical rating scale (0=no satisfaction, 10=total satisfaction).

7

Description
Cumulative post-operative analgesic consumption (e.g., NSAIDs, opioids).
Timepoint
First 48 hours post-operation
Method of measurement
Patient medical records evaluation

Intervention groups

1

Description
Intervention group: Patients in this group will receive a single 60 mg oral capsule of Duloxetine 2 hours prior to the surgery. Following the procedure, they will receive a 60 mg oral dose every 24 hours for a duration of 2 days.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive a placebo capsule, visibly identical to the intervention medication, 2 hours prior to the surgery. Post-operatively, they will receive a placebo capsule every 24 hours for a duration of 2 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorramabad Shihadaye Ashayer Hospital
Full name of responsible person
Arian Karimi Rouzbahani
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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
Khoram-Abad 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
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Position
medical doctor
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Person responsible for updating data

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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
Postoperative pain Postoperative anxiety
When the data will become available and for how

long

Timing and Duration of Data Availability The deidentified Individual Participant Data (IPD) and associated documentation for this study will become available six months after final publication of the manuscript in the target journal, through a reputable public repository (e.g., Figshare or Zenodo). Duration of availability: The data will be retained and accessible for a minimum of five years from the date of publication. Conditions of access: All applicants may request access by submitting a written request to the Principal Investigator and signing a Data Use Agreement, at no cost.

To whom data/document is available

Description of Persons and Institutions Eligible to Receive Deidentified IPD and Supporting Information The deidentified Individual Participant Data (IPD) and accompanying supporting materials (including the data dictionary, analysis methodology, and statistical reports) will be made available to all researchers, scientists, and professionals in fields regardless of whether they work in academic institutions, government agencies, industry, pharmaceutical companies, or medical technology firms. Conditions and Requirements for Access: Purpose of Use: Applicants must specify the intended purpose. Permitted uses include: academic research, medical product development, meta-analyses, health evaluations, and education. Data Use Agreement (DUA): All applicants must sign a DUA committing to use the data solely for approved purposes. Intellectual Property: The data remain the property of the original investigators. Applicants may not sell or redistribute the data. Ownership of Results: Results derived from the data belong to the requesting researcher, provided that the original investigators are acknowledged as collaborators or sources in any final publication. No Re-identification: Applicants must commit to not attempting to re-identify individuals from the deidentified dataset. Oversight: The original investigators retain oversight rights and may revoke access in case of violation. Notes: Commercial use is permitted, subject to the above terms. Uses that violate patient privacy or conflict with Iranian health and ethical regulations are prohibited.

Under which criteria data/document could be used

Data Sharing The deidentified Individual Participant Data (IPD) and associated supporting documentation from this study will be made available to all qualified researchers, without restriction based on institutional affiliation (academic, commercial, governmental, or non-profit organizations). Access conditions: Applicants must possess appropriate scientific qualifications (minimum Master's degree or equivalent). A letter of introduction from the applicant's affiliated institution is required. Signing a Data Use Agreement and committing to non-attempt of participant re-identification is mandatory. Purely commercial use requires explicit written authorization from the Principal Investigator. Permitted uses: Secondary data analysis, meta-analysis, validation studies, and any other research purposes under applicable privacy and ethical regulations. Prohibited uses: Sale or transfer of data to third parties, attempts to identify participants, and unauthorized commercial exploitation.

From where data/document is obtainable

Access Criteria and Data Sharing Mechanism Types of analyses permitted: Secondary analyses to address new research questions Meta-analyses and systematic reviews Validation studies and comparisons with similar datasets Predictive modeling or advanced statistical analyses Educational use in academic settings (with confidentiality safeguards) Criteria for evaluating requests: Scientific qualifications of the applicant: Documented research track record, publications, and relevant expertise Clarity of research objective: Submission of a clear study protocol or research proposal Scientific justification for data access: Demonstration of the necessity to access IPD Adherence to ethical principles: Commitment to non-re-identification and privacy protection No conflict of interest: Absence of commercial or competitive interests that compromise scientific integrity Access mechanism: Applicants must submit a written request to the Principal Investigator including: Brief project description (maximum 500 words) List of required data elements Letter of introduction from affiliated institution Academic CV Request reviewers: Principal Investigator and the core research team Review timeline: Maximum 4 weeks from receipt of complete application Data delivery: Following approval and signing of the Data Use Agreement, data will be provided via secure download link or confidential repository Reporting: Applicants must provide a summary of findings to the research team upon completion and properly cite the data source in any publications Grounds for rejection: Insufficient scientific justification Clear conflict of interest or unauthorized commercial use Failure to meet ethical or legal requirements

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

How to Access Data and Contact Information To request access to the study data, applicants may contact the Principal Investigator through one of the following methods: Principal Investigator: [Full Name] [Title and Institutional Affiliation] Preferred method of communication: Email Contact Information: Email: [email address] Telephone: [phone number with country code] Fax: [fax number - if available] Postal Address:[Department/Division][Institution/Hospital/University Name][Full Postal Address][City, Postal Code, Country] Online Access: Project Website: [URL - if available] Data Repository: [Repository name and URL, e.g., Figshare, Zenodo, Dryad - if available] Digital Object Identifier (DOI): [DOI for the dataset - if assigned] Required Documentation for Request: Completed application form (available via email) Research protocol or study proposal Applicant's academic CV Letter of introduction from affiliated institution Signed draft Data Use Agreement Response Time: Requests will be reviewed and responded to within 4 weeks.

Comments