# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Jul 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**

Arian Karimi Rouzbahani

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Not yet 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

**City**
Khorramabad

**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
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Arian Karimi Rouzbahani
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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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**
Khoram-Abad University of Medical Sciences
**Full name of responsible person**
Arian Karimi Rouzbahani
**Position**
medical doctor
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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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**