

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The efficacy of the ultrasound-guided retrolaminar block versus the classic paravertebral block in patients undergoing unilateral inguinal herniorraphy: a randomized controlled study

Protocol summary

Study aim

Evaluate the postoperative analgesic effects of ultrasound-guided retrolaminar block versus the classic paravertebral block in patients scheduled for elective open inguinal herniorraphy.

Design

A concealed, Prospective, blinded randomized clinical trial. Two parallel group ,25 patient in each, enrolled between January 2023, and March 2023, and followed for 24 hours.

Settings and conduct

In Mansoura university hospital , both techniques will be performed after induction of anesthesia by a single operator, ultrasound-guided using 17-gauge, 80 mm, Tuohy needle (Univer;Unisis, Tokyo, Japan). In both groups, the spinous process of T12 will be identified ,the patient in the lateral position. We will scan the paramedian anatomical landmarks of T12, ipsilateral to the surgical side, using an 8-13MHz linear array ultrasound transducer probe

Participants/Inclusion and exclusion criteria

Inclusion criteria • Age between 20 and 60 years and prepared for elective unilateral inguinal herniorraphy. ,American Society of anesthesiologists (ASA) I or II. Exclusion criteria Age beyond the previously mentioned limits ,patients refusal ,ASA > II. ,having contraindications for the study medications ,Infections at block site ,morbid obesity ,history of substance abuse ,history of allergy to local analgesics ,mental dysfunction, Metabolic disease, using anticoagulants.

Intervention groups

Retrolaminar block (RLB)(n=25) will include 25 cases who will receive 20ml of bupivacaine 0.25% , will be injected ultra-sound guided into the retrolaminar space between the lamina of T12 and the paraspinal muscles Paravertebral block(PVB)(n=25) will include the other 25 cases who will receive 20ml of bupivacaine 0.25% ,will

be injected ultra-sound guided into the paravertebral space at level of T12.

Main outcome variables

- Number of patients who needed rescue analgesia (morphine) in the first 24 h.

General information

Reason for update

Acronym

RLB

IRCT registration information

IRCT registration number: **IRCT20220212054002N2**

Registration date: **2023-01-25, 1401/11/05**

Registration timing: **prospective**

Last update: **2023-01-25, 1401/11/05**

Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

zenat eldadamony

Name of organization / entity

Mansoura university

Country

Egypt

Phone

+20 122 543 9066

Email address

zenatddd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-30, 1401/11/10

Expected recruitment end date

2023-05-30, 1402/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of the ultrasound-guided retrolaminar block versus the classic paravertebral block in patients undergoing unilateral inguinal herniorraphy: a randomized controlled study

Public title

Retrolaminar block in unilateral inguinal herniorraphy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20 and 60 years and prepared for elective unilateral inguinal herniorraphy. American Society of anesthesiologists (ASA) I or II.

Exclusion criteria:

Patients refusal ASA > II. Patients refusal having contraindications for the study medications. Infections at block site. History of substance abuse. Mental dysfunction. Metabolic disease Using anticoagulants.

Age

From **20 years** old to **60 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Enrolled patients will randomly allocated to group (RLB) and group (PVB) with allocated ratio 1:1 .Randomization will done before surgery by computer generated random ,Version28.0 . Opaque sealed sequentially numbered envelopes containing the patients` codes will used and opened just before anesthesia by physician who will not involved in the study . The patients will be allocated to either group "RLB", who receive retrolaminar block , or group "PVBB" who receive paravertebral block , with general anesthesia

Blinding (investigator's opinion)

Double blinded

Blinding description

Anesthesiologist who will perform the block will not be blinded to group assignment. However, anesthesiologist

responsible of the patient and health care providers who collected the data will be blinded to group allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Research Board

Street address

Algomhouria street

City

Mansoura

Postal code

35511

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

R.22.12.2001.R1

Health conditions studied**1****Description of health condition studied**

Post operative pain control in unilateral inguinal hernia repair

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes**1****Description**

Number of patients who needed rescue analgesia (morphine) in post operative

Timepoint

24 hour post operative period

Method of measurement

Visual Analogue Scale to measure pain

Secondary outcomes**1****Description**

Mean blood pressure ,and Heart rate

Timepoint

Basal(0), At skin incision, During sac traction, and At end of surgery.

Method of measurement

Sphygmomanometer

2

Description

Post-operative pain

Timepoint

Immediate post-operative (0) and At 2, 4,6,8,12,24 h post-operative.

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Control group:(BVB) patient will include the other 25 cases who will receive 20 ml of bupivacaine 0.25%, will be injected ultra-sound guided into the ipsilateral paravertebral space at level of T12

Category

Treatment - Other

2

Description

Intervention group: (RLB) patient will receive 20 ml of bupivacaine 0.25%, will be injected ultra-sound guided into the ipsilateral retrolaminar space between the lamina of T12 and the paraspinal muscles

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mansoura university hospital

Full name of responsible person

Zenat Eldadamony MOHAMED

Street address

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zenatddd@gmail.com

Web page address

<http://www.mans.edu.eg>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mansoura university hospital

Full name of responsible person

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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

Mansoura university hospital

Proportion provided by this source

50

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

Mansoura university hospital

Full name of responsible person

Zenat Eldadamony Mohamed

Position

lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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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

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

Title and more details about the data/document

IPD primary outcome measure only

When the data will become available and for how long

6 month after published

To whom data/document is available

Academic institutions or businesses

Under which criteria data/document could be used

Comparison

From where data/document is obtainable

Email addresses zenatddd@gmail.com

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

Request by Email

Comments