Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The efficacy of the ultrasound-guided retrolaminar block versus the classic paravertebral block in patients undergoing unilateral inguinal hernioraphy: 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 hernioraphy.

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 hernioraphy. ,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 hernioraphy: a randomized controlled study

Public title
Retrolaminar block in unilateral inguinal hernioraphy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years and prepared for elective unilateral inguinal hernioraphy. American Society of anesthesiologists (ASA) I or II.
Exclusion criteria:
Patients refusal ASA > II. Patients refusal h aving 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

Sphygmomonometer

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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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