

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

External Oblique Intercostal Plane Block Versus rectus sheath Plane Block in Supra-umbilical Surgical Incisions; Randomized Controlled Double Blinded Clinical Trial

Protocol summary

Study aim

Evaluate the postoperative analgesic effects of ultrasound-guided external oblique intercostal block versus rectus sheath block block in patients scheduled for suprabumbilical incision

Design

Double blind (participant .assessor) controlled interventional study parallel assigned ,90 patient aged more than 18 years old ,both sex , scheduled for supra-umbilical surgical incision in Mansoura university hospital ,ethical approval will be grunted

Settings and conduct

In Mansoura university hospital , both techniques will be performed after induction of anesthesia by a single operator, bilaterally with real-time ultrasonographic guidance (HFL38x/13- 6 MHz Linear Array Transducer; Sonosite M-Turbo™, Bothell, WA, USA) using a 22G (0.70 mm × 50 mm) Stimuplex® A insulated needle (B. Braun, Melsungen, Germany)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: American Society of Anesthesiologists (ASA) grade I -II, Scheduled to undergo elective supra-umbilical surgeries under GA . Exclusion Criteria: Allergy to local anesthetics, Infection at the site of injection, Coagulopathy, Chronic pain syndromes, Prolonged opioid medication, Chronic liver disease, chronic renal disease, and cognitive impairment.

Intervention groups

A high-frequency linear ultrasound probe will be placed in a longitudinal parasagittal orientation at the sixth intercostal space in the anterior midaxillary line. A 21G 10 cm needle will be inserted using an in plane approach. The tip of the needle will be placed into the fascial plane on the deep aspect of the external oblique muscle. A volume of 20 mL of LA mixture (10 mL of bupivacaine 0.5%, 5 mL of lidocaine 1% and 5 mL of normal saline to make a mixture totaling 20 ml.) will be

injected.

Main outcome variables

pain score at 1, 3,6 , 9, 12,18,21 and 24 hours postoperatively evaluated by visual analogue score.

General information

Reason for update

Acronym

EOIB

IRCT registration information

IRCT registration number: **IRCT20220212054002N3**

Registration date: **2023-08-14, 1402/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-14, 1402/05/23**

Update count: **0**

Registration date

2023-08-14, 1402/05/23

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

2023-07-22, 1402/04/31

Expected recruitment end date

2023-11-30, 1402/09/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
External Oblique Intercostal Plane Block Versus rectus sheath Plane Block in Supra-umbilical Surgical Incisions; Randomized Controlled Double Blinded Clinical Trial

Public title
External Oblique Intercostal Plane Block in Supra-umbilical Surgical Incisions

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 American Society of Anesthesiologists (ASA) physical status grade I -II Scheduled to undergo elective supra-umbilical surgeries under GA (epigastric herniotomy-gastrectomy-open cholecystectomy- nephrectomy).
Exclusion criteria:
 Allergy to local anesthetics,, Infection at the site of injection, Coagulopathy, Chronic pain syndromes Prolonged opioid medication, Chronic liver disease , or chronic renal disease, cognitive impairment.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked

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

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Enrolled patients will randomly allocated to group (EOIB) and group (RSB) 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 “EOIB”, who receive external oblique intercostal plane block , or group “RSB” who receive rectus sheath plane 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, participant

,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
 Algomhorea street
City
 Mansoura
Postal code
 35511
Approval date
 2023-08-06, 1402/05/15
Ethics committee reference number
 R.23.06.2232.R1

Health conditions studied

1

Description of health condition studied
 Post operative pain control in super umbilical surgical incision
ICD-10 code
 K87
ICD-10 code description
 umbilical surgical incision

Primary outcomes

1

Description
 POST OPERATIVE PAIN SCORE
Timepoint
 24 hours post operative
Method of measurement
 VISUAL ANALUGE SCALE

2

Description
 amount of postoperative morphine consumed
Timepoint
 24 hours post operative
Method of measurement
 milligram

Secondary outcomes

1

Description

amount of postoperative morphine consumed

Timepoint

24 hours post operative

Method of measurement

milligram

Intervention groups

1

Description

Intervention group: A high-frequency linear ultrasound probe will be placed in a longitudinal parasagittal orientation at the sixth intercostal space in the anterior midaxillary line. A 21G 10 cm needle will be inserted using an inplane approach. The tip of the needle will be placed into the fascial plane on the deep aspect of the external oblique muscle. A volume of 20 mL of LA mixture (10 mL of bupivacaine 0.5%, 5 mL of lidocaine1% and 5 mL of normal saline to make a mixture totaling 20 mL.) will be injected.

Category

Treatment - Other

2

Description

Intervention group: The rectus sheath block was performed bilaterally with real-time ultrasonographic guidance (HFL38x/13-6 MHz Linear Array Transducer; Sonosite M-Turbo™, Bothell, WA, USA) using a 22G (0.70 mm x 50 mm) Stimuplex® A insulated needle (B. Braun, Melsungen, Germany) via an in-plane approach to the rectus sheath. 10 mL of 1% lignocaine, together with adrenaline 1:200,000, and 10 mL of 0.5% bupivacaine were deposited in the potential space between the rectus abdominis muscle and the posterior rectus sheath bilaterally. A total of 30 mL of 1% lignocaine (200 mg) and 20 mL of 0.5% bupivacaine (100 mg) were administered.

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

Algomhoria street

City

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35511

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+20 100 726 8585

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mansoura university

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?

No

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

Full name of responsible person

Zenat Eldadamony

Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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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

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

Statistical Analysis Plan

Not applicable

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

Title and more details about the data/document

all collected identified IPD

When the data will become available and for how long

6 month after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

IPD and primary outcome

From where data/document is obtainable

zenatddd@gmail.com

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

email request

Comments