Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 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 suprumbilical 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 × 50 mm)Stimuplex® A insulated needle (B. Braun, Melsungen, Germany) via an in-plane approach to the rectussheath. 10 mL of 1% lignocaine, together with adrenaline 1:200,000, and 10 mL of 0.5% bupivacainewere deposited in the potential space between the rectus abdominis muscle and the posterior rectussheath 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
Mansoura
Postal code
35511
Phone
+20 100 726 8585
Fax
Email
zenatddd@gmail.com
Web page address
http://www.mans.edu.eg

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mansoura university
Full name of responsible person
Zenat Eldadamony Mohamed
Street address
Algomhoria street
City
Mansoura
Postal code
35511
Phone
+20 100 726 8585
Email
zenatddd@gmail.com
Web page address
http://www.mans.edu.eg
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

Street address
Algomhoria street
City
Mansoura
Province
Dakahalia
Postal code
35511
Phone
+20 122 543 9066
Fax
Email
zenatddd@gmail.com
Web page address
http://www.mans.edu.eg

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mansoura university
Full name of responsible person
Zenat Eldadamony Mohamed
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Anesthesiology
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Fax
Email
zenatddd@gmail.com
Web page address
http://www.mans.edu.eg

Person responsible for updating data

Contact
Name of organization / entity
Mansoura university
Full name of responsible person
Zenat Eldadamony Mohamed
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Anesthesiology
Street address
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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