

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

analgesic effect of adding calcitonin to bupivacaine in erector spine plane block for breast surgery ,double blind randomized study

Protocol summary

Study aim

Aim to assess the analgesic effect of adding calcitonin to bupivacaine in erector spine plane block

Design

Double blind randomized control trial, randomization will be done before surgery by computer generated random numbers using statistical software SPSS (IBMSPSS Version 28.0).patient allocated to control group (A) and intervention group (B)with allocation ratio 1:1 ,phase IV clinical trial ,

Settings and conduct

Main operation theater in OCMU center in Mansoura university hospital under general anesthesia, patient will receive unilateral erector spine plane block ultrasound guided in lateral decubitus position with either bupivacaine alone or bupivacaine plus calcitonin. Participant, caregiver, and investigators all are blind to the components of solution injected during block as it will be prepared by pharmacist in medication room before patient enter the room.

Participants/Inclusion and exclusion criteria

one hundred twenty female patients aged 18-65 years, American Society of Anesthesiologists physical status I and II, undergoing unilateral breast cancer surgery (modified radical mastectomy, breast conservational surgery, simple mastectomy and axillary clearance) were included. Exclusion criteria included patient refusal, history of bronchial asthma, infection at the injection site, spinal deformities, coagulation disorders, allergy to local anesthetics, history of opioid usage for chronic pain and cognitive/psychiatric disorders.

Intervention groups

Control group (group A) bupivacaine. Intervention group (group B): bupivacaine plus calcitonin.

Main outcome variables

rescue analgesia (first analgesia request), total opioid requirement (morphine in 24 hour after operation), inflammatory mediator (IL6,IL10,TNF)

General information

Reason for update

change the time interval for secondary outcome because practically it is difficult to let the patient come again after 7 days

Acronym

IRCT registration information

IRCT registration number: **IRCT20220212054002N1**

Registration date: **2022-03-18, 1400/12/27**

Registration timing: **prospective**

Last update: **2022-10-02, 1401/07/10**

Update count: **1**

Registration date

2022-03-18, 1400/12/27

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

2021-04-01, 1400/01/12

Expected recruitment end date

2022-06-30, 1401/04/09

Actual recruitment start date

2022-04-01, 1401/01/12

Actual recruitment end date

2022-06-30, 1401/04/09

Trial completion date

2022-11-30, 1401/09/09

Scientific title

analgesic effect of adding calcitonin to bupivacaine in erector spine plane block for breast surgery ,double blind randomized study

Public title

calcitonin in mastectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female patients Aged 18–65 years, American Society of Anesthesiologists physical status I and II, Undergoing unilateral breast cancer surgery (modified radical mastectomy, breast conservational surgery, simple mastectomy and axillary clearance)

Exclusion criteria:

patient refusal, history of bronchial asthma spinal deformities, coagulation disorders, allergy to local anesthetics, history of opioid usage for chronic pain cognitive/psychiatric disorders infection at the injection site

Age

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

Gender

Female

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **130**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

patients will randomly allocated to control group (A) and study group (B) 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 A pharmacist will prepare the drug mixture. The patients will be allocated to either control group— group “A”, who receive only bupivacaine , or study group— group “B” who receive calcitonin plus bupivacaine in the ESP block with general anesthesia.

Blinding (investigator's opinion)

Double blinded

Blinding description

participant ,care givers ,investigators all are blind to component of solution injected in unilateral erector spine plane block ,under ultrasound after general anesthesia .As solution will be prepared by anesthesia technician in medication room before patient enter the operation room

according to allocated randomized number .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Institutional Research Board ,IRB

Street address

Algomhorria street

City

Mansoura

Postal code

35516

Approval date

2022-01-29, 1400/11/09

Ethics committee reference number

R.21.12.1558.R1.R2-2022/01/29

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

acute post mastectomy pain and post operative inflammatory reaction

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

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

time to rescue analgesia (opioid) in post operative period

Timepoint

time point measured from the end of surgery to request of analgesic

Method of measurement

visual analogue scale to measure pain assessment of pain if VAS is more than 3 patient will receive morphine 10 Mg intramuscular and reassess after 30 min for pain relieve .

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

total opioid requirement
Timepoint
24 hour post operative
Method of measurement
amount of drug prescribed amount of morphine
consumption in Mg in 24 hour after the end of surgery

2

Description
inflammatory mediators (interleukin 6,interlokin 10, and
tumor necrotic factor
Timepoint
before intervention and 2hour post operative ,12 hour
post operative , and 24 hour post operative
Method of measurement
lab kit to measure inflammatory mediators

Intervention groups

1

Description
control group: ultrasound guided unilateral erector spine
plane block will be performed under complete aseptic
condition after induction of general anesthesia directly
and 15 min before skin incision with 100mm 21 G needle
while the patient in unilateral position ,60 patient in the
group solution used for injection will be (30 ml
bupivacaine 0.25% plus 2ml saline)
Category
Treatment - Drugs

2

Description
Intervention group: ultrasound guided unilateral erector
spine plane block will be performed under complete
aseptic condition after induction of general anesthesia
directly and 15 min before skin incision with 100mm 21
G needle while the patient in unilateral position ,60
patient in the group solution used for injection will be (30
ml bupivacaine 0.25% plus 50 IU calcitonin in 2ml saline
)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mansoura university
Full name of responsible person
Mona Gad Elebiedy
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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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Web page address
<http://irb.mans.edu.eg>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mansoura university
Proportion provided by this source
10
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**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

IPD collected for primary outcome

When the data will become available and for how long

available starting 6 month after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

academic purpose

From where data/document is obtainable

email address// zenatddd@gmail .com

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

email address

Comments