

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 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  
**Street address**  
Algomhorria  
**City**  
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**Postal code**  
35516

**Phone**  
+20 122 543 9066  
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+20 50 2267016  
**Email**  
zenatddd@gmail.com  
**Web page address**  
<https://irb.mans.edu.eg>

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Mansoura university  
**Full name of responsible person**  
Mansoura university  
**Street address**  
Al gomhoria  
**City**  
Mansoura  
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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

**Street address**

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**Province**

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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**

Lecturer

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Mansoura university hospital

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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**