Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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 trail ,

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

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+20 122 543 9066

Email address
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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 anethesia 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

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?

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

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Email
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Web page address
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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