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Does adding intravenous dexamethasone to paravertebral block augment postoperative analgesia in breast cancer patients?

Submission date
23/06/2017

Recruitment status
No longer recruiting

Registration date
29/06/2017

Overall study status
Completed

Last Edited
04/01/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breast cancer normally requires surgery as a treatment, either to remove a lump or to remove the entire breast tissue. An important aspect of surgery is the anesthetic in order to not feel pain during the operation. There are different types of anesthetics that have different benefits. A paravertebral block (PVB) is a method that provides an analgesic effect (pain control) with less sedation (a medication to put people to sleep). Adding an intravenous dexamethasone (a steroid medication that is added to the veins through a needle) could be beneficial to patients to help control inflammatory conditions when given in addition to a PVB. The aim of this study is to evaluate if intravenous dexamethasone augments the analgesic effect of paravertebral block in breast cancer surgery.

Who can participate?
Adults aged 18-80 who are undergoing surgery for breast cancer

What does the study involve?
Participants are randomly allocated to one of two groups. Participants receive the standard operating care prior to surgery. Those in the first group receive a paravertebral nerve block as well as intravenous dexamethasone added to it. Those in the second group receive the PVB only. All participants receive standard care. Participants are observed every two hours for 72 hours after surgery for pain, nausea, vomiting, side effects, and to see if any other pain medication is taken.

What are the possible benefits and risks of participating?
Participants may benefit from a longer lasting analgesic effect. There are no risks with participating.

Where is the study run from?
National Cancer Institute, Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
March 2017 to September 2017

Who is funding the study?
National Cancer Institute, Cairo University (Egypt)

Who is the main contact?
Dr Ahmed Bakeer
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Contact information

Type(s)
Scientific

Contact name
Dr Ahmed Bakeer

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201617016.2p

Study information

Scientific Title
Intravenous dexamethasone augments the analgesic effect of paravertebral block for cancer breast surgery: a prospective randomised placebo-controlled study

Study objectives
The aim of this study is to evaluate if intravenous dexamethasone augments the analgesic effect of paravertebral block in breast cancer surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of National Cancer Institute, Cairo University, 18/6/2017, ref: 201617016

Study design
Observational prospective randomised placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Female patients undergoing surgery for breast cancer

Interventions
Participants are randomly allocated to one of two groups. Participants receive the standard operating care prior to surgery.

Intervention group: Participants in this group receive a paravertebral nerve block (PVB) as well as an intravenous dexamethasone added to it. Surgery is then continued as to the standard level of care.

Control group: Participants receive the PVB and the standard care.

Participants are observed every two hours for 72 hours post-operatively for pain, nausea, vomiting, if any other analgesic taken and when sensation returns. Any side effects, nausea or vomiting are recorded for 72 hours.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
paravertebral nerve block, intravenous dexamethasone

Primary outcome measure
1. Pain is measured using the visual analogue score (VAS) at every two hours during the 72 hours post operation
2. Time of return sensation is measures using patient interviews at every two hours during the 72 hours post operation
3. Analgesic taken is measured using patient records at every two hours during the 72 hours post operation

Secondary outcome measures
1. Nausea is measured using patient records at every two hours during the 72 hours post operation
2. Vomiting is measured using patient records at every two hours during the 72 hours post operation
3. Side effects and complications measured using patient records at every two hours during the 72 hours post operation

Overall study start date
01/02/2017

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Patients for breast cancer surgery ASA1-3
2. Aged from 18-80

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Female

Target number of participants
50 patients in 2 groups

Key exclusion criteria
1. Coagulopathy
2. Allergy to drugs in study
3. Refusal to participate

4. Severe renal, hepatic or lung disease
5. Chronic opioid use

Date of first enrolment
01/03/2017

Date of final enrolment
01/08/2017

Locations

Countries of recruitment
Egypt

Study participating centre
National Cancer Institute, Cairo University
Al Kasr Al Aini
Fom Al Khalig WA Deir an Nahas
Misr Al Qadimah
Cairo Governorate
Cairo
Egypt
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Sponsor information

Organisation
National Cancer Institute, Cairo University

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
University/education

Funder Name
National Cancer Institute, Cairo University

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ahmed Baker at ahmed_bakir76@yahoo.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/12/2018		Yes	No