ISRCTN15920148 https://doi.org/10.1186/ISRCTN15920148

# 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

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)
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

## Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
80 years

### Sex
Female

### 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

**ROR**
https://ror.org/03q21mh05

# Funder(s)

**Funder type**
University/education

**Funder Name**
National Cancer Institute, Cairo University

# Results and Publications

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |