

Postoperative pain control after breast surgery

Submission date 26/04/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/06/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Breast cancer is the most common cancer in women that requires frequent surgery. Nearly 40% breast surgery patients experience significant amount of pain just after surgery, reflecting the inadequacy of conventional pain management. Most of the responses of the human body to post-surgical pain (pain after surgery) have been proven to be detrimental to the patient's homeostasis (normal body function) and recovery. Furthermore, up to 50% of breast cancer patients suffer from chronic (long lasting) pain after surgery, and inadequate pain relief (analgesia) is considered to be a reason for this. A number of therapeutic measures have been accepted as a part of a "multi-modal" approach to postoperative pain control. Thoracic paravertebral block (PVB) is used for pain relief after chest (thoracotomy) surgery and mastectomy (removal of the breast). PVB can provide profound, long-lasting deafferentation (blocking or destroying nerve cells that cause pain). Unlike general anesthesia, PVB can provide postoperative analgesia which much more effective than other forms of pain relief. It can also lead to less nausea and vomiting, a shorter recovery time, and earlier discharge from hospital. The use of PVB in patients undergoing ambulatory (outpatient) breast surgery has a cost-saving potential. Fentanyl is a synthetic (man-made) opioid with a short-acting pain killing effect that is suitable to be applied directly to the skin. The aim of this study is to study the effect of transdermal fentanyl (that is, fentanyl given through the skin) via a method called the transdermal therapeutic system (TTS). The aim of this study is to investigate the effect of transdermal fentanyl as adjuvant to paravertebral block for pain control in breast cancer surgery.

Who can participate?

Women with breast cancer scheduled for surgery.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given a Patients will be randomly classified using sealed envelope into two equal groups each of 25 transdermal fentanyl (TDF) patch three hours before their operation. Paravertebral block (PVB) is also be performed before the patient is given general anesthesia. Those in group 2 are given the PVB only. Heart rate and blood pressure are monitored before and during surgery. After surgery patients are transferred to the post-anesthesia care unit (PACU) and are monitored for vital signs, level of sedation and pain.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
March 2016 to June 2016

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

Who is the main contact?
Dr Ahmed Bakir
ahmed_bakir77@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Dr Ahmed Bakir

Contact details
National Cancer Institute, Cairo University
Kasr Al Eini Street
Fom El Khalig
Cairo
Egypt
11796
+201115661922
ahmed_bakir77@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201516015.2

Study information

Scientific Title
Transdermal fentanyl patch as an adjuvant to paravertebral block for pain control after breast cancer surgery : a randomized double blind controlled trial

Study objectives

The aim of this work is to study the effect of transdermal fentanyl as adjuvant to paravertebral block for pain control in breast cancer surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cairo University National Cancer Institutional Review Board, 22/03/2016, ref: 201516015.2

Study design

Observational study 3 months duration arandomized double blind controlled trial

Primary study design

Observational

Secondary study design

Nested case-control study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Postoperative pain (breast cancer patients)

Interventions

Patients will be randomly classified using sealed envelope into two equal groups each of 25 patients.

1. Group A: (TDF & PVB)

Patients of this group will obtain a transdermal fentanyl (TDF) patch 25 µg/h three hours before induction of anesthesia. Paravertebral block (PVB) will be performed using 20 mL of bupivacaine 0.25% then general anesthesia will be induced.

2. Group B: (PVB)

Paravertebral block will be performed using 20 mL of bupivacaine 0.25% then general anesthesia will be induced.

Heart rate and blood pressure will be measured before surgery and during the procedure itself. After surgery patients will be transferred to the post-anesthesia care unit (PACU) and will be monitored for vital signs (heart rate, blood pressure, respiratory rate, and SPO2), level of sedation and pain.

Intervention Type

Drug

Drug/device/biological/vaccine name(s)

Fentanyl

Primary outcome measure

1. The time of the first request for analgesia post surgery
2. Total analgesic consumption in the first 48 hours after surgery

Secondary outcome measures

1. Postoperative adverse effects such as nausea, vomiting, hypotension, bradycardia, and cardiac arrhythmia
2. Postoperative complications of the block including accidental pneumothorax and vascular puncture

Overall study start date

22/03/2016

Completion date

22/06/2016

Eligibility

Key inclusion criteria

Female with cancer breast with physical status ASA 1-3 scheduled for cancer breast surgery

Participant type(s)

Mixed

Age group

Mixed

Sex

Female

Target number of participants

50 participants

Key exclusion criteria

Patients with:

1. Central neuropathy
2. Coagulopathy
3. Psychiatric illness
4. History of drug abuse
5. Liver or renal impairment

Date of first enrolment

22/03/2016

Date of final enrolment

22/06/2016

Locations

Countries of recruitment

Egypt

Study participating centre

National Cancer Institute, Cairo University

Kasr Al Eini Street

Fom El Khalig

Cairo

Egypt

11796

Sponsor information

Organisation

National Cancer Institute, Cairo University

Sponsor details

Kasr Al Eini Street

Fom El Khalig

Cairo

Egypt

11796

+201115661922

ahmed_bakir77@yahoo.com

Sponsor type

University/education

ROR

<https://ror.org/03q21mh05>

Funder(s)

Funder type

University/education

Funder Name

National Cancer Institute, Cairo University

Alternative Name(s)

NCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Egypt

Results and Publications

Publication and dissemination plan**Intention to publish date**

22/06/2017

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017	24/01/2019	Yes	No