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Postoperative pain control after breast surgery

Submission date 26/04/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/06/2016	**Overall study status** Completed	
Last Edited 24/01/2019	**Condition category** Cancer	

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 though 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 25transdermal 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?
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Contact information

Type(s)
Scientific

Contact name
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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
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Sponsor information

Organisation
National Cancer Institute, Cairo University

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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