

# Postoperative pain control after breast surgery

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

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Ahmed Bakir

### Contact details

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Quality of life

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

Female

**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

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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

## Alternative Name(s)

NCI

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

Egypt

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/10/2017	24/01/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes