

# Preemptive analgesia with bupivacaine in mastectomy

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
07/02/2010	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
22/02/2010	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
01/02/2012	Cancer	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Jacek Zielinski

### Contact details

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## Additional identifiers

### Protocol serial number

001

## Study information

### Scientific Title

A randomised double-blind placebo-controlled trial of preemptive analgesia with bupivacaine in patients undergoing mastectomy for carcinoma of the breast

### Study objectives

To test a hypothesis that preemptive analgesia with bupivacaine applied in the area of surgical incision in patients undergoing mastectomy for carcinoma of the breast would reduce post-

operative acute pain and would reduce the amount of analgesics used during surgery and in post-operative period.

As of 19/03/2010 this record was updated to include the actual end date of this trial; the initial anticipated end date was 31/03/2010.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Local Ethics Committee Medical University of Gdańsk approved on the 6th July 2009 (ref: 195/2009)

### **Study design**

Prospective double-blind single centre randomised controlled trial

### **Primary study design**

Interventional

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

Treatment

### **Health condition(s) or problem(s) studied**

Breast cancer

### **Interventions**

Depending on random allocation to the specific group, on the day of surgery one of the preparations (40 ml) was prepared:

Group A: 100 mg bupivacainum hydrochloricum dissolved in 0.9 % NaCl solution

Group B (control): 0.9% NaCl

After intubation the preparation was injected subcutaneously along the intended line of incision. Fifteen minutes later surgical procedure was started.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Bupivacaine

### **Primary outcome(s)**

The quality of multimodal analgesia provided during surgical treatment is assessed in view of fentanyl consumption. In the post-operative period the insensitivity of pain is measured using Visual Analogue Score (VAS) scale ranged 0 - 10, where 0 = no pain and 10 = worst pain. The patient is assessed straight after waking from anaesthesia and at 1, 2, 3, 4, 8, 12, 16, 20, 24, 36 and 48 hours after surgery. In addition, the time of the first morphine dose delivered by patient

controlled anaesthesia (PCA), total morphine consumption and the number of attempts to launch PCA during lockout is measured. For assessment of pain insensitivity each patient receive a slide with the VAS scale.

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

1. Analysis of numerical values of pain intensity according to VAS scale summed up in the following time ranges: 0 - 4 hours, 4 - 12 hours, 12 - 24 hours, 24 - 48 hours, 0 - 12 hours and 12 - 48 hours
2. Comparison between the group of patients reporting pain (VAS 1 - 10) versus the group of patients with no pain complain (VAS = 0) and a comparison between the group of patients with no or only slight pain sensation (VAS 0 - 2) versus the group of patients with stronger pain (VAS greater than 2)
3. Amounts of morphine consumed in the following time ranges: 0 - 1 hours (from the moment of the end of the surgery till the end of the first post-operative hour), 0 - 4 hours, 0 - 12 hours, 1 - 2 hours and 4 - 12 hours

### **Completion date**

15/03/2010

## **Eligibility**

### **Key inclusion criteria**

1. Breast cancer patients in disease stage I, II and IIIA without neoadjuvant treatment
2. Patients qualified for radical modified mastectomy
3. Informed consent obtained from the patient
4. Females aged 35 - 90 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. No informed consent obtained from the patient
2. Allergy to bupivacaine or any other local analgesic agent
3. Allergy to any of the drugs used in the analgesia protocol
4. Prior surgically treatment for breast cancer
5. Patient history with treatment of chronic pain
6. Patients with any psychiatric disorders
7. Patients weight below 50 kg

### **Date of first enrolment**

12/07/2009

**Date of final enrolment**

15/03/2010

## Locations

**Countries of recruitment**

Poland

**Study participating centre**

Debinki 7

Gdansk

Poland

80210

## Sponsor information

**Organisation**

Medical University of Gdansk (Poland)

**ROR**

<https://ror.org/019sbgd69>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded (Poland)

## Results and Publications

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

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type

Details

Date created Date added Peer reviewed? Patient-facing?

<a href="#"><u>Results article</u></a>	results	01/10/2011	Yes	No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No