

Preemptive analgesia with bupivacaine in mastectomy

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacek Zielinski

Contact details
Debinki 7
Gdansk
Poland
80210

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Gdansk approved on the 6th July 2009 (ref: 195 /2009)

Study design

Prospective double-blind single centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not yet available in web format, please contact jaziel@gumed.edu.pl to request a patient information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

12/07/2009

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

Age group

Adult

Sex

Female

Target number of participants

100 (50 within each treatment group)

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)

Sponsor details

Department of Surgical Oncology

Debinki 7

Gdansk

Poland

80-210

Sponsor type

University/education

Website

<http://www.mug.edu.pl/>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Poland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/10/2011 | | Yes | No |