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Preemptive analgesia with bupivacaine in mastectomy

Submission date	Recruitment status	[_] Prospectively registered
07/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/02/2012	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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