SUPplementary REgional anesthesia in MAmma surgery (SUPREMA trial).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22294

Source
NTR

Brief title
SUPREMA trial

Health condition

Mamma surgery
Breast cancer
Borst operatie
Borstkanker

Sponsors and support

Primary sponsor: L.P.Tan
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No sponsors
Source(s) of monetary or material Support: L.P.Tan
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Intervention

Outcome measures

Primary outcome

Postoperative vomiting in the first 24 hours.

Secondary outcome

1. Postoperative nausea at entrance at entry in the recovery room and 4,8 and 24 hours after surgery (VAS score 0-10 cm);

2. Postoperative pain at entrance at entry in the recovery room and 4,8 and 24 hours after surgery (VAS score 0-10 cm);

3. Need for postoperative opiates (frequency and total dose in first 24 hours);

4. Need for postoperative anti-emetics (frequency and total dose in first 24 hours).

Study description

Background summary

Rationale:
The incidence of postoperative nausea and vomiting (PONV) varies from 20 to 80% in patients undergoing mamma surgery. PONV are strongly related to postoperative pain. PONV are also well known side effects of opioids. Appropriate pain management during and after surgery without, or with a lower dose of opioids, may decrease the incidence of PONV. Earlier studies with different surgical operations showed that combining general anesthesia with regional infiltration anesthesia with a long acting local anesthetic provided superior and prolonged analgesia, compared with general anesthesia alone.
Therefore, regional infiltration anesthesia of the mamma with a long acting local anesthetic could provide better analgesia in mamma surgery under general anesthesia compared to the same surgery under general anesthesia alone. This may lead to decreased incidence of PONV and decreased postoperative use of opiates and anti-emetics. Ropivacaine is chosen as a long acting local anesthetic because of its superior toxicological profile compared to bupivacaine.

Hypothesis:
In mamma surgery, regional infiltration anesthesia with ropivacaine 0,75% added to general anesthesia causes less postoperative pain, nausea and vomiting compared to general

anesthesia alone.

Study design:
Double blind, placebo controlled randomized intervention study.
Study population: Women scheduled in the Reinier de Graaf Groep for single-sided breast conserving surgery with or without sentinel node biopsy.

Intervention:
Regional infiltration anesthesia of the ipsilateral breast with ropivacaine 0,75% (maximum volume 0,47 ml/kg) or placebo (a comparable volume of NaCl 0,9%).
The regional infiltration consists of deep subcutaneous infiltration parallel to the clavicle, in the ipsilateral parasternal line and in a line parallel to and 0-1 cm posterior of the ipsilateral anterior axillary line. The infiltration trajects are from medial to lateral alongside the clavicle and from caudal to cranial at the trunk.

Main objectives:

Primary objectives:

Postoperative vomiting in the first 24 hours.

Secondary objectives:

postoperative nausea at entry in the recovery room and 4, 8 and 24 hours after surgery
postoperative pain at entry in the recovery room and 4, 8 and 24 hours after surgery
need for postoperative opiates (frequency and total dose in first 24 hours),
need for postoperative anti-emetics (frequency and total dose in first 24 hours).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The burden associated with participating consists of three subcutaneous injections with a total maximum dose of 3,5 mg/kg (0,47 ml/kg) of ropivacaine 0,75% or the same volume of NaCl 0,9%. Injections will be given under general anesthesia (which is already part of operating procedure).

Participation in this study includes side effects of infiltration anesthesia: inadvertent intravascular injection, bleeding in the infiltration traject and ipsilateral pneumothorax or numbness in the ipsilateral arm, due to brachial plexus involvement. Side effects of ropivacaine use are mostly caused by systemic administration (when inadvertently injected intravascular) and include convulsions, hypotension and nausea. Hypotension and nausea are in general frequently seen with operations and it is impossible to distinguish them as side effects of the clinical situation from side effects of the drug or field block.

The risk of these side effects can be minimized by thorough training of the anesthesiologists participating in the study.

Study objective

The incidence of postoperative nausea and vomiting (PONV) varies from 20 to 80% in patients undergoing mamma surgery. PONV are strongly related to postoperative pain. PONV are also well known side effects of opioids. Appropriate pain management during and after surgery without, or with a lower dose of opioids, may decrease the incidence of PONV. Earlier studies with different surgical operations showed that combining general anesthesia with regional infiltration anesthesia with a long acting local anesthetic provided superior and prolonged analgesia, compared with general anesthesia alone.
Therefore, regional infiltration anesthesia of the mamma with a long acting local anesthetic could provide better analgesia in mamma surgery under general anesthesia compared to the same surgery under general anesthesia alone. This may lead to decreased incidence of PONV and decreased postoperative use of opiates and anti-emetics. Ropivacaine is chosen as a long acting local anesthetic because of its superior toxicological profile compared to bupivacaine.

Study design

1. At entry recovery room;

2. 4, 8 and 24 hours after end of surgery.

Intervention

Regional infiltration anesthesia of the nerve branches of the mamma subjected to surgery with ropivacaine 0,75% (maximum volume 0,47 ml/kg) or placebo (a comparable volume of NaCl 0,9%).
The regional infiltration consists of deep subcutaneous infiltration parallel to the clavicle, in the ipsilateral parasternal line and in a line parallel to and 0-1 cm posterior of the ipsilateral anterior axillary line. The infiltration trajects are from medial to lateral alongside the clavicle and from caudal to cranial at the trunk.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women;

2. One-sided breast conserving surgery with or without sentinel node biopsy;

3. Age 18-80 yr.

Exclusion criteria

1. Known allergy to amide type local anesthetics;

2. Severe liver failure;

3. Weight >120 kg;

4. Double-sided mamma surgery;

5. Infections in the infiltration region;

6. Breast conserving surgery combined with plastic surgery;

7. Pregnancy or lactation;

8. Use of opiates;

9. Use of anti-emetics.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2007
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-02-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1605
NTR-old	NTR1687
Other	METC ZWH : 08-060
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A