The influence of supplementary regional infiltration anesthesia with ropivacaine on postoperative pain, nausea and vomiting in patients undergoing mamma surgery under general anesthesia

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To investigate that in mamma surgery, regional infiltration with ropivacaine 0,75% added to general anaesthesia causes less postoperative pain, nausea and vomiting compared to general anaesthesia alone.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON35556

Source
ToetsingOnline

Brief title
SUPplementary REgional anesthesia in MAmma surgery (SUPREMA trial)

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders
- Breast therapeutic procedures

Synonym
nausea and vomiting, pain

Research involving

Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Astra Zeneca,Er worden 100 flacons Naropin gratis beschikbaar gesteld door de fabrikant (idem in vraag G2). Mogelijk zal er een beroep gedaan worden op het subsidiefonds van de Reinier de Graaf Groep.

Intervention

Keyword: anaesthesia, breast, infiltration, regional

Outcome measures

Primary outcome

postoperative vomiting in the first 24 hours

Secondary outcome

Postoperative nausea 4,8 and 24 hours after start of surgery (VAS score 0-10)

Postoperative pain 4,8 and 24 hours after start of surgery (VAS score 0-10)

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

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

Study description

Background summary

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 objective

To investigate that in mamma surgery, regional infiltration with ropivacaine 0,75% added to general anaesthesia causes less postoperative pain, nausea and vomiting compared to general anaesthesia alone.

Study design

doubleblind placebo controlled randomized intervention study

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.

Study burden and risks

The burden associated with participating consists of three subcutaneous injections with a total maximum volume of 0,47 ml/kg (with a maximum dose of 300 mg) of ropivacaine 0,75% or the same amount 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 are mainly caused by systemic administration and include convulsions, hypotension and nausea. Hypotension and nausea are frequently seen with operating procedures and it is impossible to distinguish them as side effects due to the clinical situation from side effects caused by the drug or field block.
The risk of these side effects can be minimized by careful injection and therefore thorough training of the anesthesiologists participating in the study will be performed .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

women
one-sided breast conserving surgery with or without sentinel node biopsy
age 18-80 yr

Exclusion criteria

known allergy to amide type local anesthetics
severe liver failure
weight >120 kg
double-sided breast surgery
infections in the infiltration region

breast conserving surgery combined with plastic surgery
pregnancy/lactation
use of opiates
use of anti-emetics

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2008
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Naropin
Generic name:	ropivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	09-06-2008
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-07-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	25-03-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-04-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
Other	1687
EudraCT	EUCTR2008-003161-89-NL
CCMO	NL16755.098.08