Efficacy of a mamma fieldblock in oncological breast surgery in reducing postoperative nausea and pain.

Published: 15-08-2007
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Reducing postoperative pain and nausea improves patient satisfaction.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30861

Source
ToetsingOnline

Brief title
Efficacy of a mamma fieldblock in oncological breast surgery.

Condition

- Breast therapeutic procedures

Synonym
postoperative pain and nausea

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: wetenschapsfonds afdeling anesthesie CWZ;stichting Morpheus

Intervention

Keyword: breast surgery, field block, postoperative pain

Outcome measures

Primary outcome

Postoperative opioidconsumption. Postoperative pain, nausea and vomiting are

scored using a numeric rating scale.

Secondary outcome

No secundary study parameters/outcome of the study defined

Study description

Background summary

Improving postoperative care after oncological breast surgery.

Study objective

Reducing postoperative pain and nausea improves patient satisfaction.

Study design

Double blinded, randomized study

Intervention

Mamma fieldblock.

Study burden and risks

Fieldblock is performed under general anesthesia.
Risk of toxicity is minimalized by perfoming the block lege artis. Like any puncture hematomes are possible.

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

Female patients for lumpectomy or ablatio mammae with of without axillary lymphnode dissection.

Exclusion criteria

Allergy to local anesthetics. Chronic use pain medication.

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:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	80
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2007-001368-59-NL
CCMO	NL17026.091.07