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

Published: 15-08-2007 Last updated: 08-05-2024

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

Public

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Scientific

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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