

Comparison of continuous local anaesthetic and systemic pain treatment after axillary lymphadenectomy in breast carcinoma patients - a prospective randomized study. (CCLAA)

First published: 06/04/2015

Last updated: 06/04/2015

Study

Finalised

Administrative details

EU PAS number

EUPAS9209

Study ID

9210

DARWIN EU® study

No

Study countries

 Slovenia

Study description

BACKGROUND: Acute pain after axillary lymphadenectomy is often related mainly to axillary surgery. The aim of the prospective randomized study was to find out if continuous wound infusion of local anaesthetic reduces postoperative pain, consumption of opioids and the incidence of chronic pain compared to the standard intravenous piritramide analgesia after axillary lymphadenectomy in breast carcinoma patients. **METHODS:** Altogether 60 patients were enrolled in the prospective randomized study, half in wound infusion of local anaesthetic and half in the standard (piritramide) group. **RESULTS:** In the recovery room and on the first day after surgical procedure, the wound infusion of local anaesthetic group reported less acute and chronic pain, a lower consumption of piritramide and metoclopramide, but their alertness after the surgical procedure was higher compared to the standard group. **CONCLUSIONS:** After axillary lymphadenectomy in breast carcinoma patients, wound infusion of local anaesthetic reduces acute pain and enables reduced opioid consumption, resulting in less postoperative sedation and a reduced need for antiemetic drugs. After wound infusion of local anaesthetic there is a statistical trend for reduction of chronic pain.

Study status

Finalised

Research institutions and networks

Institutions

[Institute of Oncology Slovenia](#)

First published: 01/02/2024

Last updated: 01/02/2024

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2010

Actual: 15/06/2010

Study start date

Planned: 01/12/2010

Actual: 01/12/2010

Data analysis start date

Planned: 09/12/2011

Actual: 09/12/2011

Date of final study report

Planned: 25/09/2012

Actual: 25/09/2012

Sources of funding

- Other

More details on funding

National health insurance

Study protocol

[EUPAS9209-9206.pdf](#) (357.94 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Clinical trial

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The aim of the prospective randomized study was to find out if continuous wound infusion of local anaesthetic reduces postoperative pain, consumption of opioids and the incidence of chronic pain compared to the standard intravenous piritramide analgesia after axillary lymphadenectomy in breast carcinoma patients.

Study Design

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Medical condition to be studied

Pain

Postoperative analgesia
Pain management
Prophylaxis of nausea and vomiting

Population studied

Short description of the study population

Breast carcinoma patients receiving continuous local anaesthetic and systematic pain treatment after axillary lymphadenectomy.

Age groups

- Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
 - Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)
-

Special population of interest

Other

Special population of interest, other

Breast cancer patients

Estimated number of subjects

60

Study design details

Outcomes

After axillary lymphadenectomy in breast carcinoma patients, wound infusion of local anaesthetic reduces acute pain and enables reduced opioid consumption, resulting in less postoperative sedation and a reduced need for antiemetic drugs.

Data analysis plan

The student t-test or the Mann-Whitney U test was conducted according to the data distribution. The association between categorical variables was tested by chi2 or Fisher's exact test, as appropriate. All comparisons were two-sided and a p-value of ≤ 0.05 was considered statistically significant.

Documents

Study results

[rado-47-02-145.pdf](#) (436.78 KB)

Study report

[EUPAS9209-9208.pdf](#) (307.33 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No