Does a continuous local anaesthetic pain treatment after immediate tissue expander reconstruction in breast carcinoma patients more efficiently reduce acute postoperative pain - a prospective randomised study (DCLAE)

First published: 06/04/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS9215

Study ID

9216

DARWIN EU® study

No

Study countries

Slovenia

Study description

Background:Immediate breast reconstruction with an expander is a reasonable option for properly selected patients. After reconstruction, patients have severe postoperative pain, which responds poorly to opioids. Our aim was to evaluate if continuous wound infusion of a local anaesthetic into the surgical wound reduces postoperative pain, consumption of opioids and incidence of chronic pain compared to standard intravenous piritramide after primary breast reconstruction in breast carcinoma patients.Methods:Altogether, 60 patients were enrolled in our study, one half in the group with wound infusion of a local anaesthetic, and the other half in the standard (piritramide) group. Parameters measured included: pain intensity (visual analogue scale), drug requirements, alertness, hospitalisation, side-effects and late complications. A p-value of < 0.05 was considered statistically significant.Results:In the recovery room, the test group reported less acute pain at rest(P=0.03) and at activity (P= 0.01), and on the day of the surgical procedure they reported less pain at activity (P= 0.003). Consumption of piritramideand metoclopramide was lower in this group (P< 0.0001), but their alertness after the surgical procedure was higher compared to the standard group (P< 0.001). After three months, the test group reported less chronic pain (P=0.01).Conclusions:After primary tissue expander breast reconstruction, wound infusion of a local anaesthetic significantly reduces acute pain and enables reduced opioid consumption, resulting in less postoperative sedation and reduced need for antiemetic drugs. Wound infusion of a local anaesthetic reduces chronic pain.

Study status

Finalised

Research institutions and networks

Institutions

Institute of Oncology Slovenia

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Institution

Contact details

Study institution contact

Branka Strazisar bstrazisar@onko-i.si

Study contact

bstrazisar@onko-i.si

Primary lead investigator

Branka Strazisar

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2010

Actual: 15/06/2010

Study start date

Planned: 24/01/2011

Actual: 24/01/2011

Data analysis start date

Planned: 15/10/2012

Actual: 15/10/2012

Date of final study report

Planned: 17/09/2013

Actual: 17/09/2013

Sources of funding

- Other

More details on funding

National health insurance

Study protocol

EUPAS9215-9212.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:

Aim was to evaluate if continuous wound infusion of a local anaesthetic into the surgical wound reduces postoperative pain, consumption of opioids and incidence of chronic pain compared to standard intravenous piritramide after primary breast reconstruction in breast carcinoma patients.

Study Design

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Medical condition to be studied

Pain management

Postoperative analgesia

Prophylaxis of nausea and vomiting

Population studied

Short description of the study population

Breast carcinoma patients receiving continuous local anaesthetic pain treatment after immediate tissue expander reconstruction.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Breast cancer patients

Estimated number of subjects

60

Study design details

Outcomes

Ater primary tissue expander breast reconstruction, wound infusion of a local anaesthetic significantly reduces acute pain and enables reduced opioid

consumption, resulting in less postoperative sedation and reduced need for antiemetic drugs. Wound infusion of a local anaesthetic reduces chronic pain.

Data analysis plan

Prior data indicated that the failure rate among controls was 0.5. If the true failure rate for experimental subjects is 0.15, 27 experimental subjects and 27 control subjects are needed to be able to reject the null hypothesis that the failure rates for experimental and control subjects are equal, with probability (power) of 0.8. The type-I error probability associated with this test of the nullhypothesis is 0.05.The Student t-test or the Mann–Whitney U-test was used according to data distribution. The association between categorical variables was tested by the chi-square test or Fisher's exact test, as appropriate. All comparisons were two-sided and a P-value <0.05 was considered statisticallysignificant.

Documents

Study results

wso.pdf (137.02 KB)

Study, other information

EUPAS9215-9214.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