Chronic pain after breast cancer surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20830

Source
NTR

Brief title
N/A

Health condition

Chronic pain, breast cancer, surgery, sensitisation, mechanism, cox-2, quantitative sensory testing

Sponsors and support

Primary sponsor: 03-06-2009 update: UMC St. Radboud and Bernhoven Hospital
Source(s) of monetary or material Support: Pfizer

Intervention

Outcome measures

Primary outcome

Neuroplasticity, e.g. central sensitisation as demonstrated by quantitative sensory testing, at one month after surgery.

Secondary outcome

1. Neuroplasticity at other time points after surgery;

2. Acute and chronic clinical pain measures (pain scores, analgesic consumption, pain questionnaires);

3. Other pain outcome measures (incidence of phantom pain, pain maps, analgesia complications);

4. Surgical outcome measures (complications);

5. Patient satisfaction and well-being (including nausea and vomiting, opioids symptom distress score SDS).

Study description

Background summary

Breast surgery for cancer is associated with both tissue and nerve damage, and is frequently followed not only by acute, but also by chronic pain, causing significant medical and social morbidity. The nociception of surgery is now recognised to result in postoperative hyperalgesia via changes in central nervous system processing (central sensitisation). Such neuroplasticity is mediated both via humoral (tissue damage leading to inflammation) and neuronal (nerve damage leading to neuropathy) nociceptive inputs. Postoperative hyperalgesia will lead to increased pain, which - together with nerve damage - has recently been linked to subsequent pain chronification in a number of studies. Based on animal studies, it is now accepted that a major mechanism for such pain chronification is the persistence of (abnormal) central sensitisation.

The aim of this study is to investigate the interaction between extended perioperative COX-2 inhibition (starting before surgery and continuing 5 days into the postoperative period) and extended locoregional block (paravertebral block) using local anaesthetics on central sensitisation after breast surgery. This should enable us to gain insight into the relative contributions of humoral (inflammatory) and neuronal (neuropathic) nociceptive inputs to acute postoperative hyperalgesia, persistence of central sensitisation and pain chronification after breast surgery. The defined primary study endpoint is the persistence and extent of central sensitisation one month after breast surgery as measured by quantitative sensory testing. The study will further investigate effects on clinical pain and other outcome measures, and determine their relationship to measures of central sensitisation.

Study objective

To study the effect of the interaction of cyclooxygenase-2 (COX-2) inhibition (started preoperatively and continued 5 days into the postoperative period) and extended local anaesthetic blockade via paravertebral block on postoperative central sensitisation after breast surgery for malignancy.

Study design

1. At formal recruitment before surgery;

2. On leaving recovery unit postoperatively (inpatient; not measures 6-7);

3. 5, 15 days postoperatively (outpatient);

4. 1, 3, 6 and 12 months post-mastectomy (outpatient);

5. 12 months post-mastectomy, we will additionally collect details on.

Intervention

After informed patient consent, patients will be randomised to either an active or placebo treatment group. On the morning of surgery, the patient will receive oral midazolam premedication (7.5 mg). In the operating theatre, the patients randomised to the active group will receive an i.v. injection of parecoxib 40 mg 30 minutes before the start of surgery. The injection will be repeated 6 hours later. On the evening of the operation day patients will start celecoxib 2 X 200mg/d and continue this scheme until the morning of the fifth postoperative day. The placebo group will receive placebo injections and tablets according to the same regime. As the medication will be blinded, neither observers nor persons involved in patient management nor observers will be aware of which group the patients are in.

Contacts

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Eligibility criteria

Inclusion criteria

110 patients (n=55 per group) due to undergo elective first surgery for malignancy of the breast at UMC St. Radboud or Bernhoven Ziekenhuis in Oss.

Exclusion criteria

1. Previous breast surgery;

2. Any type of chronic pain syndrome;

3. Regular analgesic medication (including opioids, NSAIDs or COX-2 inhibitors) for the 2 weeks preceding surgery;

4. Pre-existing central nervous system pathology (e.g. stroke, dementia);

5. Conditions predisposing to neuropathy (e.g. diabetes mellitus, alcohol abuse);

6. Inability to comply with testing procedures or to give informed consent;

7. Presence of contra-indications to COX-2 therapy (e.g. impaired renal or cardiac function (including angina pectoris), untreated hypertension, active or recent gastrointestinal ulceration);

8. Contraindications to paravertebral blockade.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2006
Enrollment:	110
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-05-2009
Application type:	First submission

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
NTR-new	NL1692
NTR-old	NTR1793
Other	ethical committee CMO region Arnhem-Nijmegen : CMO-nr. 2004/239
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A