Chronic pain after breast cancer surgery.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20830

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: 03-06-2009 update: UMC St. Radboud and Bernhoven Hospital
Overige ondersteuning: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-05-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A