Analgesia and nerve function following pulsed radiofrequency for postmastectomy pain.

No registrations found.

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

Summary

ID

NL-OMON29287

Source
NTR

Brief title
PRF4PMPS

Health condition

Postmastectomy pain
pulsed radiofrequency, breast cancer, post surgical pain

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: NKI-AVL

Intervention

Outcome measures

Primary outcome

The primary endpoint is the difference in intensity of pain with 90° abduction of the ipsilateral shoulder before and 3 weeks following PRF as measured by the Numerical Rating Scale [NRS]

(0=no pain and 10=worst imaginable pain) and the daily dose of analgesics.

Secondary outcome

Secondary endpoints are changes in sensory disturbances of the thoracic wall and / or axilla as measured by Quantitative Sensory Testing (QST) according to the protocol of the German Research Network on Neuropathic pain, the globally perceived effect of the treatment [Likert scale 7 P= 75% improvement - Very good, 6P = 50–74% improvement – Good, 5P = 25–49% improvement - Fairly good, 4P = 0–24% improvement or worse - Same as before, 3P = 25–49 % worse - Fairly bad, 2P = 50–74% worse – Bad, 1 P = 75% worse - Very bad] and the duration of the analgesic effect in weeks.

Study description

Background summary

About one third of the women undergoing breast surgery for cancer develop chronic postmastectomy pain (PMPS) in their axilla and chest wall. PMPS is a neuropathic pain syndrome that is predominantly caused by a lesion of the intercostobrachial nerve during surgery. As the pain is typically exacerbated by arm movements and lying on the painful side and is accompanied by allodynia, PMPS has considerable impact on daily functioning, quality of sleep and sexual life.

The standard treatment of PMPS with antidepressants, capsaicine-crème and TENS often gives poor painrelief or has unacceptable side effects. Alternatively, the isothermal radiofrequency treatment known as pulsed radiofrequency (PRF) may be used to relieve neuropathic pain. PRF is widely used as a treatment option for neuropathic pain in the Netherlands. However the effect of PRF on PMPS has not been shown yet. In addition the effect of PRF on nerve function has not been evaluated yet.

Evaluation of efficacy of pulsed radiofrequency on the intensity of pain in patients with PMPS for more than six months after surgery.

Primary endpoint is the intensity of pain at rest and with 90° abduction of the ipsilateral shoulder 3 weeks following PRF of the ipsilateral thoracic dorsal root ganglia Th1/Th6 and the daily dose of analgesics.

Secondary endpoints are changes in sensory disturbances of the thoracic wall and or axilla as measured via quantitative sensory testing, the impact of PRF on daily functioning and the duration of the analgesic effect.
In a prospective double-blind randomized placebo-controlled trial are assigned to receive PRF of the thoracic dorsal root ganglia Th 6 or Th 1 respectively or a sham-intervention.

Following a positive test block at the ipsilateral spinal nerves Th1 or Th 6 patients receive at

these spinal nerves DRGs or a Sham treatment with the same procedure only without administration of energy.

The intervention studied is frequently performed for the treatment of neuropathic pain without any complications that can be attributed to pulsed radiofrequency. The only risks of the treatment is adherent to the placement of the electrode and the applicated lidocaine, ie pain at the puncture site, pneumothorax due to accidental puncture of the pleura and allergic reaction to lidicaine. In some patients the intensity of PMPS increases intermittently. Pneumothorax is the most serious hypothetic complication. It has not occured in the personal experience of the study ccordinator (AL) and is not described in the literature. To keep this risc as low as possible the electrode is placed onder fluroscopy and patients are controled for dyspnoe 30 min following PRF treatment.

Analysis for the primary end-point will include all randomized patients based in the 'intention-to-treat'. Descriptive statistics will be given to characterize the patients in the intervention and in control group. The primary endpoint will be analyzed using the T-tests or, if data are seriously not-normally distributed tested by means of an appropriate non-parametric procedure.

Study objective

The aim of this study is the evaluation of efficacy of PRF on the intensity of pain in patients with PMPS for more than six months after surgery with the hypothesis that PRF reduces the intensity of pain more than 50%. In addition, the precise evaluation of afferent nerve function via Quantitative Sensory Testing (QST) before and after treatment will be performed in order to obtain information on prognosis possible mode of action of PRF related to subgroups based on neuropathic pain phenotype.

Study design

3 weeks, 6 months, 1 year after the treatment.

Intervention

Pulsed radiofrequency treatment of the thoracic spinal nerves Th1 and/or 6 as suggested by a testblock with lidocaine.

The control group receives a Sham treatment with the same procedure only without administration of energy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Chronic neuropathic pain (>6 m duration) of the anterior chest wall and/or axilla following unilateral breast surgery for cancer. Neuropathic pain being defined as “pain arising as direct consequence of a lesion or disease affecting the somatosensory system” of definite or probable certainty;

2. Pain intensity > 4 according to the Numerical Rating Scale (NRS);

3. > 50% reduction of pain-intensity following test-block of the ipsilateral spinal nerve TH 1 in subjects with predominant axillary pain or spinal nerve TH 6 with predominant pain of the thoracic wall;

4. Age 18-65 years.

Exclusion criteria

1. Proven metastases;

2. Impaired coagulation;

3. Non-surgery related pain of the chest wall;

4. Other diseases impairing nerve function;

5. Psychiatric disease, dementia;

6. Bilateral breast surgery;

7. Former PRF treatment of PMPS;

8. Language barriers and other problems impairing the reliable completion of questionnaires;

9. No written informed consent.

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):	01-07-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33543
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2497
NTR-old	NTR2614
CCMO	NL26023.031.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33543

Study results

Summary results
Lukas A, Perez RSGM: Pulsed radiofrequency treatment for postmastectomy pain. Der Schmerz 2009, 23:103.