Analgesia and nerve function following pulsed radiofrequency for postmastectomy pain

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33543

Source
ToetsingOnline

Brief title
pulsed radiofrequency for postmastectomy pain

Condition

- Other condition

Synonym
postmastectomy pain syndrome

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: analgesia, postmastectomy pain, pulsed radiofrequency, QST

Outcome measures

Primary outcome

The primary endpoint is the intensity of pain with 90° abduction of the ipsilateral shoulder 3 weeks following PRF 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.

Socioepidemiological data (age, weight, marital state, number of children, employment, highest academic degree)

Clinical parameters (type of surgery, anesthesiologic management, postoperative pain, surgical complications postoperative, additional oncological treatments,

precise onset en duration of pain, development of PMPS, additional chronic

pain localisations)

Fear and depression [HADS] [24]

Impact of pain on daily activities [VRS 0=not at all, 1=a little, 2=moderately,

3=quite a lot, 4=a lot] [8]

Quality of life [SF-36] [25]

Adverse events and symptoms out [VRS 0=not at all, 1=a little, 2=moderately,

3=quite a lot, 4=a lot]

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.

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

In a prospective double-blind randomized placebo-controlled trial patients are assigned to receive PRF of the thoracic dorsal root ganglia Th 6 or Th 1 respectively or a sham-intervention.
See attatchment for flow scheme of the study

Intervention

The C-arm of the fluoroscopy unit is positioned with the beam vertical to the axis of the intervertebral foramen. The entry point is located by projecting a metal ruler over the caudal part of the foramen. The 22 G cannula (SMK Pole needle 100 mm with 4 mm active tip, Cosman International) is introduced parallel to the beam and, if necessary, the position is corrected in the superficial subcutaneous layers. The fluoroscope is then adjusted to the lateral view and the cannula is inserted further until the tip projected over the middle or lower dorsal third of the intervertebral foramen. The stylet of the cannula is then replaced by the RF probe (SMK-TC 10, Radionics, Burlington, MA). After checking the impedance, indicating a normal, closed electrical circuit, stimulation is performed at a frequency of 50 Hz to obtain a sensory stimulation threshold in all patients. If paresthesias are elicited along the tested thoracic nerve root with less than 0.3 V an adequate proximity of the DRG (Ford et al., 1984) is achieved. PRF current of 45 V/ 140 mA with pulses of 2 Hz and 20 ms duration is then applied for 6 min generator (Cosman RFG-1B Lesion Generator)

Study burden and risks

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. 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18-65 years
Chronic pain (>6 m duration) of the anterior chest wall and / or axilla following breast surgery for cancer
Pain intensity > 4 according to NRS
At least one other sensory symptom indicating the neuropathic nature of the pain
> 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.

Exclusion criteria

Proven metastases
Impaired coagulation
Non-surgery related pain of the chest wall
Other diseases impairing nerve function

Psychiatric disease, dementia
Language barriers
No written informed consent

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	10-07-2009
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	14-02-2014

Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29287
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL26023.031.09
OMON	NL-OMON29287