Effectiveness of Botulinum Toxin Infiltration for treatment of upper limb dysfunctions after treatment for breast cancer.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26807

Source
NTR

Brief title
Botox in breast cancer patients

Health condition

Patients treated for breast cancer and chronic pain (> 3 months) at the breast region

Sponsors and support

Primary sponsor: UZ Leuven
Source(s) of monetary or material Support: UZ Leuven

Intervention

Outcome measures

Primary outcome

The primary outcome is the evolution of pain at the breast region.

Secondary outcome

- Pain-pressure thresholds of the pectoral muscles and shoulder girdle muscles
- Shoulder mobility
- Shoulder function
- Shoulder alignment
- Quality of life

Study description

Study objective

Breast cancer patients with chronic pain at the breast region will have a greater decrease in pain after a botulinum toxin infiltration, an individual physical therapy programme and home exercise programme than patients who reveive a saline solution infiltration, an individual physcial therapy programme and home exercise programme.

Study design

- baseline (before the botulinum toxin or placebo infiltration)
- 1 month (= short term effects of the infiltration)
- 3 months (= after physical therapy programme)
- 6 months (= after the home programme and end of the study)

Intervention

- botulinum toxine (experimental group) /saline solution infiltration (control group) at baseline
- at baseline start of 3 months of individual physical therapy programme (1x/week) (mobilisations, stretching, scar tissue massage, exercise therapy)
- after individual 3 months home programme with mobilizing and stretching exercises

Contacts

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Eligibility criteria

Inclusion criteria

- women after breast cancer with unilateral axillary lymph node dissection or sentinel node biopsy; mastectomy (with or without autologous reconstruction) or wide excision of the tumour
- adjuvant chemotherapy and/or radiotherapy finished for at least 3 months
- Pain at the breast region for at least 3 months

Exclusion criteria

- Patients with metastasis and patients who cannot participate during the entire study or patients who are mentally or physically not able to participate in the study are excluded
- Cases were no injection is possible in the pectoral muscle (e.g. reconstruction with a tissue expander) are excluded as well.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4804
NTR-old	NTR4944
Other	EC UZ Leuven : s57283

Study results