Compression vest for the treatment of symptomatic breast/chest wall edema in breast cancer patients

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The aim of this pilot study is to study if there is an effect on pain, QoL and the amount of breast edema of wearing a compression vest, in order to determine whether a large randomized study is feasible.

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

Summary

ID

NL-OMON42450

Source
ToetsingOnline

Brief title
Breast edema compression vest

Condition

- Other condition
- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
Breast edema, lymph edema

Health condition

Borstoedeem

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Thuasne

Intervention

Keyword: Breast cancer, Compression vest, Edema, Quality of life

Outcome measures

Primary outcome

Primary endpoint is the course of patient reported pain over a 6 month period.

Secondary outcome

Secondary endpoints are the course of degree of breast edema and quality of

life over a 6 month period.

Study description

Background summary

Due to better treatment options and earlier detection of breast cancer, survival rates continue to increase. As such, (late) treatment toxicity, quality of life and cosmetic outcome are becoming more important. Treatment has become less mutilating after breast conserving surgery combined with whole-breast irradiation (i.e. breast conserving therapy (BCT)) became the primary therapy for women with early stage breast cancer. However, an increasingly common complication of BCT is breast edema, which may lead to chronic pain, but also reduced quality of life (QoL) and poor cosmetic outcome. When pain is present most patients are currently treated with physical therapy, but evidence of its effectiveness is still low and a gold standard does not yet exist. A downside of physical therapy is that patients have to undergo the therapy regularly and treatment might even has to continue for years after symptoms and treatment started. Another treatment option is a compression vest with the potential, apart from reducing symptoms, to improve self-efficacy in patients because they decide when to wear it without the need to visit therapists. However effectiveness of the compression vest has not yet been objectified in studies.

Study objective

The aim of this pilot study is to study if there is an effect on pain, QoL and the amount of breast edema of wearing a compression vest, in order to determine whether a large randomized study is feasible.

Study design

A pilot study.

Intervention

Compression vest.

Study burden and risks

Patients who are wearing the vest may experience relief of breast edema related symptoms. In terms of burden, they might experience a tight feeling on the skin while wearing the vest, which could also be the case when treated with compression therapy and taping by a physical therapist. This tight feeling can be overcome by changing the vest to a larger size. All patients will fill out questionnaires upon inclusion, at 2 weeks, and 1, 3 and 6 months. This will take approximately 10-15 minutes per follow-up moment. Patients will have to visit the hospital at baseline and 1, 3 and 6 months after they started wearing the vest (i.e. 25 minute consult with physical examination, photo documentation of the breast and short basic follow-up questions), and it is expected that additional measurements for fitting a new compression vest will need to be taken 2-5 times during participation in the study. Those fitting measurements will be performed at a location as desired by the patient (e.g. UMC Utrecht or at patients* home).

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

- Females, aged 18 years and older.
- Patient treated with surgery and/or radiotherapy for breast cancer, with symptomatic breast edema (e.g. pain).
- Visual Analog Scale (VAS) pain score of 3 or more.

Exclusion criteria

- Inability to understand the Dutch language.
- Indicated to undergo radiation treatment of the breast/chestwall within the next 6 months.
- Cardiac complaints.
- Pacemaker.
- Port-a-cath.
- Thrombosis of the arm.
- Pulmonary embolism.
- Pulmonary disease.
- Pregnancy.
- Non-breast cancer related lymph edema.
- Clinical depression or anxiety disorder.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Compression vest (Lymphatrex Bandage)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-10-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL53275.041.15