Treatment of breast cancer-associated lymphedema. A randomized study of the (cost-)effectiveness of manual lymphatic drainage and/or intermittent pneumatic compression

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON30736

Source
ToetsingOnline

Brief title
Evaluation of treatment of breast cancer-associated lymphedema.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Skin and subcutaneous tissue therapeutic procedures
- Lymphatic vessel disorders

Synonym
Lymphedema

Research involving

Human

Sponsors and support

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

Intervention

Keyword: (Cost-)effectiveness, Breastcancer, Lymphedema, Treatment

Outcome measures

Primary outcome

The primary outcome measure will be percentage reduction in the excess limb volume. The normal limb acts as the patient*s own control. Inverse water volumetry (gold standard for measuring limb volume) will be used to quantify limb volume.

Secondary outcome

Health care costs will be measured and evaluated. For this we refer to the HTA-methodology study. The quality of life will be measured by means of two validated instruments at the time of enrolment, after completing the treatment, and at 6 months after inclusion: functional assessment of cancer therapy (FACTB) with the FACTB Plus 4 subscale, and the EuroQol-50.

Study description

Background summary

In the Netherlands breast cancer is diagnosed in approximately 11500 women every year. The life-time probability of developing breast cancer is 9-10%. In the Netherlands it is the most common cancer in females.1 Lymphedema is the most frequent complication after the treatment for breast cancer. Recent studies show an incidence of 20,7% following surgical treatment for breast

cancer.6 Persons with lymphedema suffer from a severe morbidity, and loss of quality of life. In the Netherlands lymphedema is an underestimated problem. Most medical doctors hardly recognize the disease, and are not familiar with or unaware of the
different therapeutic options.

Study objective

Objective of the study is to evaluate the different therapeutic options of lymphedema. Which treatment strategy is most cost-effective in the management of patients with breast cancer associated lymph edema: manual lymphatic drainage alone, intermittent pneumatic compression alone, or a combination of both therapies in one treatment program? The results of this will support the standardisation of the treatment of lymphedema.

Study design

This is a randomized controlled study.

Intervention

Manual lymphatic drainage (MLD) is performed 3 times a week during 30 minutes, completed by multilayered compression bandages. It is performed by certified edema therapists, according to the Dr. Vodder-method. Through the pumping and stretching effect on the lymph vessels, the Dr. Vodder method of MLD stimulates the contraction of lymph vessels, helping to move the lymph forward and drain the connective tissue.

Intermittent pneumatic compression (IPC) is performed with a six or twelve-chamber circular manchet, which is placed around the arm. It is filled by means of a pneumatic pump with air, with a maximal inflating pressure of 60 mmHg (normal
maximal pressure in lymphedema), during two hours. They inflate from distal to proximal, thereby producing a wave of pressure that ascends the extremity. The edema is replaced proximally via the interstitium. It needs to be completed with multilayered compression bandages to prevent the edema coming back.

After obtaining written consent, patients are randomized to one of three treatment groups. In group I, patients will receive MLD performed by an edema therapist, completed with compressive multilayered bandages, three times a week. In group II, patients are treated with IPC at the department of dermatology, completed with compressive multilayered bandages, three times a week. In group III, patients are treated with the combination of subsequently MLD, performed by an edema therapist, and IPC, completed with compressive multilayered bandages, three times a week.

After each treatment session its effect will be evaluated by measuring the circumference of the arm at defined localizations on the arm. In the three groups the treatment will be ended if in three subsequent treatment sessions no further volume reduction of the affected arm can be accomplished anymore. Then a class II therapeutic elastic garment will be measured.

Study burden and risks

Not applicable.

Contacts

Public
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL
Scientific
Academisch Ziekenhuis Maastricht

Postbus 5800
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Untreated lymphedema in one arm, developed after treatment for breast cancer.
An increase in the volume of the affected arm >= 20% compared with the non-affected arm.
Lymphedema developed >= 12 weeks after surgical treatment for breast cancer (axillary lymph node dissection and/or axillary radiation included).

Exclusion criteria

Bilateral lymphedema.
Breast cancer recurrence.
Active clinical infection.
Deep venous thrombosis.
Pre-existent lymphedema.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	207
Type:	Anticipated

Medical products/devices used

Generic name:	Intermittent pneumatic compression device: Lymphapress
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-07-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL15111.068.07