Improving quality of survivorship for breast cancer-related lymphedema by lymphatic microsurgery: A randomized controlled trial

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To assess the effectivity of LVA on arm volume in comparison to standard therapy after 12 months.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Spleen, lymphatic and reticuloendothelial system disorders
Study type	Interventional

Summary

ID

NL-OMON43537

Source
ToetsingOnline

Brief title
BCRL-LVA study

Condition

- Spleen, lymphatic and reticuloendothelial system disorders

Synonym
Breast cancer-related lymphedema (BCRL), swollen arm

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cost-Effectiveness, Lymphedema, Microsurgery, Quality of life

Outcome measures

Primary outcome

- Excess limb volume (ELV) after 12 months

Secondary outcome

- The cost-effectiveness and quality of life.

- Quality of life

- The discontinuation rate of conservative treatment after LVA

- Arm mobility and strength

- Lymph transport measured by lymphoscintigraphy

- The difference in ELV after 24 months

Study description

Background summary

Early breast cancer detection and concomitant advancements in treatment options have not only resulted in an increase of breast cancer survival rates, but also in disease-related morbidities. In other words, an increasing number of women are living with the side effects of breast cancer treatment, making the quality of survivorship an increasingly important goal. Breast cancer-related lymphedema (BCRL) is one of the most underestimated complications of breast cancer treatment, of which the onset can occur at any time after primary cancer treatment with a reported incidence of 30% to 40% after axillary lymph node dissection (ALND) and 7% after sentinel lymph node biopsy (SLNB). Although the axillary treatment regimens are changing with a focus on less aggressive axillary treatment in order to reduce morbidity without compromising survival, BCRL will still remain a relevant problem in the future. This study aims to improve the quality of breast cancer survivorship by reducing/eliminating one of the most debilitating upper-body morbidities related to breast cancer treatment: chronic lymphedema.

Study objective

To assess the effectivity of LVA on arm volume in comparison to standard therapy after 12 months.

Study design

A multicenter, randomized controlled trial carried out in the Maastricht University Medical Center, VieCuri Medical Center and Zuyderland Medical Center.

Intervention

In this RCT patients are randomized over two arms: the first group will continue standard of care conservative lymphedema therapy, while the second group will undergo lymphatic microsurgery known as lympho-venular anastomoses (LVA) by a plastic surgeon.

Study burden and risks

The patients randomized to the microsurgical group are subject to minor surgical complications (infection, bleeding, failure of lymphatic system restoration), which is a one-time risk during the course of this study. Patients are exposed to a radiation dose of 0.3 mSv divided over 3 lymphoscintigraphies during the two year study period. After randomization the follow-up moments will be at 1, 3, 6, 12 and 24 months. A follow-up moment includes an interview and a medical examination. During this examination, the upper limbs will be assessed for sensory, motor, strength and mobility changes. Furthermore, we will measure the volume of the treated and untreated side using the water displacement method and circumference measurement. Subjects will also be asked at certain time points to fill in five questionnaires: *Lymphedema Functioning, Disability and Health (Lymph-ICF)*, *European Organization for Research and Treatment of Cancer QLQ-C30 *, *European Organization for Research and Treatment of Cancer QLQ-BR23*, *EQ-5D-5L* and the *Disabilities of the arm, shoulder and hand (DASH)* questionnaire. Lastly, a lymphoscintigraphy will be made at inclusion and after 12 months at the MUMC+.

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

- Woman over 18 years old
- Treated for early stage breast cancer and underwent an SLNB, ALND or axillary radiotherapy
- Early stage lymphedema of the arm (stage 1 -- 2b on ISL classification) with viable lymphatic vessels as determined by nearly infrared imaging
- Excess limb volume >=10%
- Followed three months conservative therapy (standard of care) according to best available care, this will be judged by skin therapists in our region
- Primary breast cancer
- Unilateral disease / treatment

Exclusion criteria

- Male sex
- Stage 3 lymphedema of the arm with evident fat deposition and/or fibrosis
- History of earlier lymph reconstruction efforts
- Recurrent breast cancer
- Distant breast cancer metastases
- Bilateral disease / treatment
- Medical history of cancer

- Primary congenital lymphedema
- Non-viable lymphatic system as determined by lymphoscintigraphy at inclusion

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-07-2016
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
ClinicalTrials.gov	NCT02790021
CCMO	NL56477.068.16