Improving the quality of life of patients with breast cancer-related lymphedema by lymphaticovenous anastomosis (LVA): A randomized controlled trial

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The primary objective of this randomized controlled trial is to study the effectiveness of lymphaticovenous anastomosis (LVA) compared to complex decongestive therapy (CDT) in terms of health-related quality of life (HRQoL). Secondary objectives are...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spleen, lymphatic and reticuloendothelial system disorders
Study type	Interventional

Summary

ID

NL-OMON55376

Source
ToetsingOnline

Brief title
LYMPH-trial

Condition

- Spleen, lymphatic and reticuloendothelial system disorders

Synonym
Breast cancer-related lymphedema; swollen arm

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: ZonMw

Intervention

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

Outcome measures

Primary outcome

The primary outcome is health-related quality of life after 12 months follow-up measured with the Lymph-ICF questionnaire.

Secondary outcome

Secondary outcomes are (in)direct costs, QALYs, cost-effectiveness ratio, the discontinuation rate of conservative treatment, and excess limb volume.

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.

Study objective

The primary objective of this randomized controlled trial is to study the effectiveness of lymphaticovenous anastomosis (LVA) compared to complex decongestive therapy (CDT) in terms of health-related quality of life (HRQoL). Secondary objectives are to compare LVA to CDT in terms of cost-effectiveness, the discontinuation rate of compression stockings, and the change in excess arm

volume.

Study design

A multicenter randomised controlled trial (RCT) consisting of two treatment groups: conservative treatment (group A) and LVA (group B). The study is conducted in Maastricht University Medical Center, Radboud University Medical Center, Zuyderland Medical Center and Canisius-Wilhelmina Hospital.

Intervention

Patients will be randomized into two groups. One group will receive conservate therapy and the second group will undergo lymphatic microsurgery by lymphaticovenous anastomosis (LVA).

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. The patients will have a total of 6 control visits: at inclusion, after 3, 6, 12, 18, and 24 months. During a visit, patients will undergo a physical examination, the volume of the arms will be measured and two questionnaires (Lymph-ICF and EQ-5D-5L) have to be filled out. A visit takes approximately 60 minutes.

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

- Women over 18 years old
- Treated for early stage breast cancer and who underwent a sentinel lymph node biopsy, axillary lymph node dissection or axillary radiotherapy
- Early stage lymphedema of the arm (ISL classification stage I/IIa; pitting edema without fibrosis) with viable lymphatic vessels as determined by indocyanin green (ICG-) lymphography
- Already received at least three months of complex decongestive therapy (currently in the maintenance phase) prior to inclusion
- Primary breast cancer
- Unilateral lymphedema
- Informed consent

Exclusion criteria

- Male sex
- Late stage lymphedema of the arm (ISL classification IIb/III lymphedema) with evident fat deposition and/or fibrosis
- History of earlier lymph reconstruction efforts
- Recurrent breast cancer
- Distant breast cancer metastases
- Bilateral lymphedema
- Primary congenital lymphedema
- Non-viable lymphatic system as determined by ICG lymphography

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:	Recruiting
Start date (anticipated):	11-01-2019
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2018
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	NL67059.068.18