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The effectiveness of compression therapy in mild arm lymphedema

Submission date	Recruitment status	[_] Prospectively registered
21/05/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/05/2023	Circulatory System	

Plain English summary of protocol

Background and study aims

Breast cancer-related arm lymphedema (BCRL) is abnormal swelling that can develop as a side effect of breast cancer surgery and/or radiation therapy. It can become a chronic condition and deterioration can be expected without treatment. Early diagnosis and treatment of mild BCRL is important as moderate/severe BCRL is associated with larger arm volumes, symptoms of tension and heaviness in the arm, and can lead to physical, psychological and social consequences and low health-related quality of life (HRQOL) BCRL can be treated by wearing a compression garment but this procedure has been described as a major problem by patients, and there is also a cost for the health care system, and often for the patient. Only a few studies have examined how the use of compression sleeve can prevent the increase in arm volume and affect symptoms and HRQOL, and more knowledge is needed. The aim of this study is therefore to examine if there is a difference in the number of participants that show improvement or worsening of mild BCRL after 6 months treatment with compression vs no compression, and to examine differences in lymphedema volume, local tissue water and subjective symptoms between the groups, as well as disease-specific HRQOL.

Who can participate?

Women treated for unilateral (one-sided) breast cancer, operated with axillary node dissection (to remove lymph nodes from the armpit), and diagnosed with mild arm lymphedema

What does the study involve?

Participants are randomly allocated to compression treatment or no compression treatment. All women are given routine information about the importance of physical activity and exercise, weight control, skin care and instructions in simple lymphatic drainage. The compression treatment group wear compression sleeves daily for 6 months. Measurements of arm volume, local tissue water and subjective symptoms are performed at start and after 1, 2, 3 and 6 months. Also, two study-specific and one disease-specific questionnaires are completed, and data are retrieved from participants' medical records.

What are the possible benefits and risks of participating?

Participants may benefit from not having to wear a compression garment in the non-compression group and all participants are carefully monitored during the study to detect

deterioration as soon as possible and start or change treatment. The participants have to spend time on some extra visits compared to the usual treatment.

Where is the study run from?
Skane University Hospital, Lund and Karolinska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2014 to May 2019

Who is funding the study?
Swedish Cancer Foundation (Sweden)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
19-0166PJ

Study information

Scientific Title
Early intervention with compression treatment of mild breast cancer-related arm lymphedema: a prospective randomized controlled intervention study

Study objectives
Early intervention with a compression sleeve prevents progression and reduces mild breast cancer-related arm lymphedema (BCRL) more than no compression. Women with mild BCRL have mild subjective symptoms and a small impact on perceived health-related quality of life (HRQOL). Wearing an arm sleeve may reduce disease-specific HRQOL.

Aims:
1. To examine if there is a proportional difference of regression/progression of arm lymphedema in women with mild BCRL, during 6 months treatment with compression vs no compression.
2. To examine differences in lymphedema volume, local tissue water, subjective symptoms during 6 months treatment with compression vs no compression.
3. To examine HRQOL in women with mild arm lymphedema at 6 months.
4. To examine differences in HRQOL if treated with compression vs no compression at 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/07/2014, Regional Ethical Review Board, Lund Sweden (Östra Vallgatan 14, Box 133, 22100 Lund, Sweden; +46 (0)46 2224180; registrator@etikprovning), ref: 2014/399

Primary study design
Interventional

Study design
Multicenter randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lymphedema

Interventions
Women diagnosed with mild arm lymphedema are consecutively randomized to the non-compression (NCG) group or compression group (CG) at the Lymphedema Unit, Skåne University Hospital and at the Physiotherapy Cancer Unit, Karolinska University Hospital, by two of the

authors. Each participant is randomly assigned to either the NCG or the CG by picking a sealed envelope, in which the group allocation is stated. The randomization is done in blocks of 10 (allocation ratio of 1:1). The examinations, information/advice and prescription of compression sleeves are made by two of the authors and by two other experienced lymphedema therapists.

The intervention group use compression sleeves daily for 6 months. All women in both groups are given routine information about the importance of physical activity and exercise, weight control, skincare and instructions in simple lymphatic drainage. For ethical reasons, the non-compression group start to wear the compression sleeve if lymphedema relative volume (LRV) increases by more than 2% from the start of the study. All participants with LRV of more than 10% drop out and receive more extended treatment.

Intervention Type
Other

Primary outcome(s)
1. The number (proportion) of women with mild breast cancer-related lymphedema BCRL (defined as Lymphedema Relative Volume [LRV] <8%) exceeding LRV >2% from start or anytime exceeding LRV >10%, measured by the water displacement method (WDM) at baseline and after 1, 2, 3 and 6 months
2. Health-related quality of life (HRQL) measured using the Lymphedema Quality of Life Inventory (LyQLI) at 6 months

Key secondary outcome(s)
1. Arm volume measured by the water displacement method (WDM), local tissue water by Tissue Dielectric Constant (TDC) and subjective symptoms of pain, tension, and heaviness by Visual Analogue Scale (VAS) at baseline and 1, 2, 3, and 6 months
2. Background data including surgical methods and adjuvant treatments collected from medical records and a study-specific questionnaire at baseline
3. Frequency of self-rated physical activity level/exercise and housework collected from a study-specific questionnaire at baseline and at 6 months
4. Frequency of use of compression and performance of simple lymphatic drainage collected from a study-specific questionnaire at 6 months

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. Women treated for unilateral breast cancer
2. Axillary node dissection
3. Diagnosed with mild arm lymphedema

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
Female

Total final enrolment
75

Key exclusion criteria
1. Recurrent breast cancer
2. Concurrent diseases that could interfere with the measurement of lymphedema
3. Cognitive disability
4. Language difficulties making it hard to participate in the study

Date of first enrolment
01/09/2014

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Skane University Hospital
Department of Hematology
Oncology and Radiation Physics
Lymphedema Unit
Lund
Sweden
22185

Study participating centre
Karolinska University Hospital
Department of Physiotherapy Cancer
Stockholm
Sweden
17176

Sponsor information

Organisation
Lund University

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Charity

Funder Name
Swedish Cancer Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
Data will be saved anonymously at Karolinska Institute and Skåne University Hospital in accordance with Swedish ethical rules. Study protocols and participant IDs are stored separately and locked in a file cabinet. Only researchers that are involved in the project will have access to the data. All participants have given written informed consent.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/06/2022	08/06/2022	Yes	No
Results article		21/05/2023	22/05/2023	Yes	No