

Health-related quality of life in postmastectomy lymphedema patients

Submission date 27/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/04/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/09/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Lymphedema is a long term (chronic) health condition that results in swelling of body tissues, most commonly developing in the arms or legs. It is caused by a problem with the lymphatic system, a network of vessels and glands important in fighting infection and removing excess fluid from body tissues. Secondary lymphedema is caused by damage to the lymphatic system or issues with the draining of excess fluid; this is often due to an infection, injury or cancer treatment. The condition is common in women treated for breast cancer, the damage often the result of surgery or radiotherapy. The swelling (edema) commonly affects the arm, leading to discomfort, reduced arm movements, pain and diminished quality of life. Quality of life of a patient with lymphedema after a mastectomy (surgery to remove the breast) is an important consideration when treating breast cancer survivors. The aim of this study is to see whether an exercise and home program in addition to conventional treatment results in a better quality of life among postmastectomy lymphedema patients.

Who can participate?

Women aged between 50 and 70 that have had a mastectomy for breast cancer and have developed lymphedema as a result.

What does the study involve?

Participants are allocated to one of two groups depending on whether are assessed for the study on Monday or Wednesday. Those assessed on Monday are assigned to the conventional therapy (CT) group. Those assessed on Wednesday are assigned to the complete decongestive therapy (CDT) group. Participants in the CT group are given manual lymphatic drainage, a low elastic compression garment, gleno-humeral mobilization (a technique for moving the shoulder joint) and deep breathing exercises. Participants in the CDT group are given manual lymphatic drainage, a compression garment, remedial exercises and a home program. Both groups receive treatment 5 times a week for 6 weeks. Their pain and quality of life are assessed at the start of the study and then 4 and 6 weeks into the study.

What are the possible benefits and risks of participating?

The participation is voluntary and there are no potential risks of participation. Benefits may include an improvement in quality of life after treatment.

Where is the study run from?

Maharishi Markendeshwar University Hospital (India)

When is the study starting and how long is it expected to run for?

June 2013 to July 2014

Who is funding the study?

King Saud University (Saudi Arabia)

Who is the main contact?

Mrs Syamala Buragadda

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RGP-VPP-256-1

Study information

Scientific Title

Effect of complete decongestive therapy and home program on health-related quality of life in post mastectomy lymphedema patients.

Study objectives

Remedial exercises and home program in addition to manual lymphatic drainage and compression bandaging results in better quality of life among postmastectomy lymphedema patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Maharishi Markendeshwar University Ethical Committee, Haryana, 07/09/2013, ref: MMU/MMIPR /013

Study design

This is a mixed factorial design that includes both between and within subjects variables

Primary study design

Interventional

Secondary study design

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Postmastectomy lymphedema

Interventions

Sixty participants were divided into two groups: conventional treatment (CT) group and complete decongestive therapy (CDT) group.

A systematic random sampling procedure was used to include the participants into the study. Volunteer participants assessed on Monday were assigned to the conventional therapy (CT) group, whereas participants assessed on Wednesday were assigned to the complete decongestive therapy (CDT) group. Each group comprised of 30 participants.

1. Conventional therapy (CT) group participants received manual lymphatic drainage, low elastic compression garment, gleno-humeral mobilization and deep breathing exercises
2. Complete Decongestive Therapy (CDT) group received manual lymphatic drainage, compression garment worn 23 hours daily, remedial exercises and a home program

Both groups received treatment 5 times a week for 6 weeks.

Intervention Type

Mixed

Primary outcome measure

1. Pain measured using the visual analogue score (VAS) at baseline, 4th week and 6th week
2. Health-related Quality of Life, evaluated with the EORTC QLQ C30 and EORTC QLQ-BR23 questionnaires

Measurements were taken at baseline, 4 and 6 weeks.

Secondary outcome measures

Quality of life measured using European Organization of Research and Treatment for Cancer quality of life questionnaire (EORTC QLQ-C30) and the EORTC QLQ-BR23 breast cancer-specific questionnaire.

Measured at baseline, 4th week and 6th week.

Overall study start date

30/06/2013

Completion date

01/07/2014

Eligibility

Key inclusion criteria

1. Females aged between 50 and 70 years
2. Unilateral mastectomy for stage I and II breast cancer
3. Completed radiotherapy and chemotherapy sessions
4. Developed lymphedema more than 3cm compared to contralateral extremity

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

60

Key exclusion criteria

1. Primary lymphedema
2. Bilateral lymphedema

3. Pulmonary edema
4. Congestive heart failure
5. Contraindications limiting therapy

Date of first enrolment

01/07/2013

Date of final enrolment

01/04/2014

Locations

Countries of recruitment

India

Study participating centre

Maharishi Markendeshwar University Hospital

Mullana University Road

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Sponsor information

Organisation

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Sponsor type

University/education

ROR

<https://ror.org/02f81g417>

Funder(s)

Funder type

University/education

Funder Name

King Saud University

Alternative Name(s)

, KSU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Saudi Arabia

Results and Publications

Publication and dissemination plan

Plans for publication in BMC Women's health.

Intention to publish date

04/05/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/05/2016		Yes	No