Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of physiotherapy combined with manual lymphatic derenage massage with physiotherapy alone and manual lymphatic derenage massage alone on pain and volume of upper limb on breast cancer patients with lymphedema: A randomized controlled trial study

Protocol summary

Study aim

Comparing the effect of physiotherapy combined with manual lymphatic derenage massage with physiotherapy alone and manual lymphatic derenage massage alone on pain and volume of upper limb and improving quality of life on breast cancer patients with lymphedema

Design

The clinical trial has control and intervention groups, randomized, phase 3, on 84 patients. Patients are randomly blok to groups.

Settings and conduct

This research will be done in the Department of Physiotherapy of Mashhad University of Medical Sciences. Patients are selected by random clinical trial method and divided into three equal groups: physiotherapy treatment group with MLD massage (PT+MLD), physiotherapy treatment group (PT) and treatment group with MLD massage (MLD). In the PT+MLD group, upper limb and neck physiotherapy is performed first, then MLD massage is performed on the upper limb of the affected side and the lymph nodes of the body, and the patient will be taught physical therapy exercises in a way that the patient can perform. In the PT group, upper limb and neck physiotherapy is performed, then physiotherapy exercises will be taught to the patient. In the MLD massage group, massage of the upper limbs will be performed for patients.

Participants/Inclusion and exclusion criteria

Female patients with lymphedema of at least 10% compared to healthy limb At least six months have passed since the patient's cancer treatment Having moderate physical activity in daily activities

Intervention groups

1.group physiotherapy and MLD massage 2.group physiotherapy 3.group MLD massage

Main outcome variables

NRS scale AROM sholder The size of the affected limb and the healthy limb will be measured with a tape measure. Upper limb functional index (ULFI) Questionnaire Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH) Questionnaire Lymphedema Life Impact Scale (LLIS) Questionnaire

General information

Reason for update

Acronym

درمان ترکیبی فیزیوتراپی کامل اندام فوقانی و گردن به همراه ماساژ MLD

IRCT registration information

IRCT registration number: **IRCT20230121057168N1**
Registration date: **2023-07-01, 1402/04/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-01, 1402/04/10**
Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Shima Eftekhar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 557 2560

Email address

shima37.eftekhar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-06-05, 1402/03/15
Expected recruitment end date
2024-02-04, 1402/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of physiotherapy combined with manual lymphatic derenage massage with physiotherapy alone and manual lymphatic derenage massage alone on pain and volume of upper limb on breast cancer patients with lymphedema: A randomized controlled trial study

Public title
Comparing the effect of physiotherapy combined with manual lymphatic derenage massage with physiotherapy alone and manual lymphatic derenage massage alone on pain and volume of upper limb on breast cancer patients with lymphedema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Female patients with lymphedema of at least 10% compared to healthy limb At least six months have passed since the patient's cancer treatment Having moderate physical activity in daily activities
Exclusion criteria:
Active malignancy Recurrence of breast cancer high blood pressure Uncontrolled heart disease Patients with bilateral lymphedema venous insufficiency Low physical activity and inability to perform daily activities
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
block randomization Patients are assigned to three groups to physiotherapy control group, massage control group, and PT+MLD intervention group using closed envelopes with block randomization method. In this way, it is divided into 6 states in 4 blocks. And each of these situations is randomly selected from the closed envelopes, and 4 people are assigned to the control and intervention groups based on the selected state of the closed envelope. The same process until the allocation of all participants in PT control groups, MLD massage control and PT+MLD intervention groups continue.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
school of paramedian sciences and health school
Street address
Yazdan building , Sadeghiyeh 18, sadeghiyeh bulv
City
Mashhad
Province
Razavi Khorasan
Postal code
9186391111
Approval date
2022-12-24, 1401/10/03
Ethics committee reference number
IR.MUMS.FHMPM.REC.1401.173

Health conditions studied

1

Description of health condition studied
Lymphoedema
ICD-10 code
197.2
ICD-10 code description
Postmastectomy lymphoedema syndrome

Primary outcomes

1

Description
The pain of patients is evaluated with the NRS scale.
Timepoint
Befor treatment After 15 sessions after 1 month
Method of measurement
The pain of patients is evaluated with questionnaire of the NRS scale.

2

Description
The size of the affected limb and the healthy limb will be measured.
Timepoint

Befor treatment After 15 sessions after 1 month

Method of measurement

The circumference of the uper limb is measured using a tape measure

Secondary outcomes

1

Description

ROM of the upper limb joints is measured.

Timepoint

Befor treatment After 15 sessions after 1 month

Method of measurement

The range of motion of the shoulder is measured using a goniometer.

2

Description

The performance of patients is evaluated.

Timepoint

Befor treatment After 15 sessions after 1 month

Method of measurement

The performance of patients is evaluated using the Upper Limb Functional Index (ULFI) questionnaire.

3

Description

The degree of disability of the patients is evaluated.

Timepoint

Befor treatment After 15 sessions after 1 month

Method of measurement

The degree of disability of the patients is evaluated with the Shortened Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH).

4

Description

Quality of life of patients will be examined.

Timepoint

Befor treatment After 15 sessions after 1 month

Method of measurement

Quality of life of patients will be examined using the Lymphedema Life Impact Scale (LLIS) questionnaire.

Intervention groups

1

Description

Intervention group: Lymphatic drainage manual massage + physiotherapy In the intervention group of physiotherapy + MLD massage, patients are initially subjected to FES electrical stimulation for 20 minutes with an edema reduction program, in the next stage they undergo upper limb and neck physiotherapy treatment for 20 minutes, then to For 20 minutes, MLD massage will be performed on the affected upper limb and all lymph nodes. Physiotherapy in this group includes (3,17): First, the following exercises are performed for the patients in all sessions. and grade 1 and 2 mobilization for neck vertebrae, distraction, Inf glide, Pos glide shoulder in grade 1 and 2 distraction and mobilization of elbow and wrist in grade 1 and 2 Pumping in flexion and extension for fingers, wrist, elbow and shoulder exercises below In the third session, the patient is taught to do them under the supervision of the physiotherapist, then the patient is asked to continue the exercises at home on a daily basis. Diaphragmatic breathing exercise with expansion of the lungs and Outward ribs, abdomen and Lower back Ext while inhaling and exhaling with the nose and Inward ribs, abdomen and Lower back flexion, shoulder rotation movements with the help of a bar in full flexion, abduction and adduction, perform patterns Bilateral PNF along with trunk rotation, Upright position correction and postural exercises, Chin tuck, Shoulder shrug_Scapular retraction/adduction, resistance exercises including weight lifting with light weight for patients who are between one to three times in the direction of flexion and extension, abduction and adduction, internal rotation and external Do rotation for both elbow and shoulder joints (in case of ROM limitation, it will start with a low range and then it will progress). Resistance exercises will start with light weights, then heavier weights will be used. Also, in the advanced stages of the exercise, theraband with high elastic resistance will be used. After physiotherapy, MLD massage in the supine position on the sternum, neck, respectively. and the face, the underarm area of the opposite side, the underarm area of the affected side, and then transferring lymph from the underarm area of the affected side to the healthy side, and then massaging the groin on the healthy side and then the affected side, and transferring lymph from the underarm area of the affected side to the lymph nodes of the groin same side After these steps, the MLD massage is performed in a rotatory manner on the abdomen, then the patient is placed in a prone position and massage is performed from the affected armpit area to the healthy armpit area and massage from the armpit area of the affected lymph nodes to the batok area of the same side. is done After performing these steps, the patient is supine and MLD massage in the upper limb, respectively from the elbow area to the shoulder and armpit area, from the back of the wrist to the forearm, then from the back of the wrist to the shoulder, and in the next step, the wrist area to the Elbow and then from the wrist area towards the shoulder. All stages of Stroking massage are performed 15 times in each area. The duration of this massage will be about 20 minutes (12).

Category

Rehabilitation

2

Description

Control group: Physiotherapy In the physiotherapy control group, patients are initially subjected to FES electrical stimulation for 20 minutes with the edema reduction program, then according to the mentioned method, upper limb and neck physiotherapy will be performed for the patient for 20 minutes.

Category
Rehabilitation

3

Description
control group: In the control group of MLD massage, patients are initially subjected to FES electrical stimulation for 20 minutes with the edema reduction program, then MLD massage will be performed on the involved upper limb and all lymph nodes for 20 minutes according to the mentioned method.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Medical Research Training Center
Full name of responsible person
Gholam Ali Mamouri
Street address
Ahmed Abad St., Ghaem Medical Research Training Center
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3801 2465
Email
MaamouriGh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
Street address
University Street, Mashhad University of Medical Sciences, Research and Technology Deputy
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
ghaourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Neda Mostafaee
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Azadi Square, Mashhad University of Medical Sciences, Faculty of Paramedicine
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948964
Phone
+98 51 3884 6710
Email
neda_mostafaee@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Shima Eftekhar
Position
Master Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Khayam Blv,Khayam 40,Ghavami18,Number 24
City
Mashhad

Province
Razavi Khorasan
Postal code
9196744549
Phone
+98 51 3763 0685
Email
shima37.eftekhar@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Shima Eftekhar
Position
Master Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Khayam Blv,khayam 40,Ghavami 18,Number 24
City
Mashhad
Province
Razavi Khorasan
Postal code
9196744549
Phone
+98 51 3763 0685
Email
shima37.eftekhar@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Comparing the effect of physiotherapy combined with manual lymphatic derenage massage with physiotherapy alone and manual lymphatic derenage massage alone on pain and volume of upper limb on breast cancer patients with lymphedema: A randomized controlled trial study
When the data will become available and for how long
06.12.2023
To whom data/document is available
researchers
Under which criteria data/document could be used
To investigate better treatment for lymphedema
From where data/document is obtainable
Popmed database
What processes are involved for a request to access data/document
Article search
Comments