

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of combined decongestive therapy with and without Pilates exercise on the expression of inflammatory biomarkers and body measurement in breast patients with upper extremity lymphedema

Protocol summary

Study aim

This trial aimed to explore the effect of combined decongestive therapy and Pilates exercise on expression of CA15-3 antigen, edema volume, shoulder range of motion and quality of life in breast cancer patients with unilateral upper extremity lymphedema.

Design

This clinical trial, conducted randomly on 30 patients. there were 15 people in the control group and 15 people in the intervention group.

Settings and conduct

Patients referring to a Lymphedema clinic in Tehran were included. First, patients were requested to participate in this study. If they were agreed, then they were assessed for eligibility criteria. Then, one who was in charge of randomization was called to allocate patients to control or intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with unilateral lymphedema, stage II patients without history of using complete decongestive therapy having no regular exercise during the last six month, menopausal woman, no infection in the arm and no severe skin redness, no taking anticoagulants, no nerve injuries in the upper extremity, no history of heart failure, no history of kidney disease, no paralysis in the hand or arm, no cancer recurrence.

Intervention groups

In control group, a total of 21 sessions of combined decongestive therapy were performed daily. Each session consisted of 40 minutes. Appropriate skin care methods including moisturizing and using multi-layered short stretch bands were used. In intervention group, in addition to combined decongestive therapy, patients had exercise for 6 weeks (5 days weekly) for 40-30 minutes. 10 warm-up exercise and then the main movements were performed with purpose of strengthening the muscles of hands and shoulders.

Main outcome variables

Inflammatory biomarkers and peykometry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200421047158N1**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **retrospective**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

Registration date

2021-01-07, 1399/10/18

Registrant information

Name

Roghaya Mokhtari hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 5223 5720

Email address

r.hesari1353@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-30, 1399/03/10

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

2020-05-30, 1399/03/10

Actual recruitment end date

2020-07-31, 1399/05/10

Trial completion date

2020-10-21, 1399/07/30

Scientific title

The effect of combined decongestive therapy with and without Pilates exercise on the expression of inflammatory biomarkers and body measurement in breast patients with upper extremity lymphedema

Public title

Exploring the effect of combined decongestive therapy and Pilates exercise on the reduction of lymphedema symptom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with unilateral lymphedema, stage II Patients without history of using complete decongestive therapy Having no regular exercise during the last six month Menopausal women No infection in the arm and no severe skin redness Not taking anticoagulants No nerve injuries in the upper extremity No history of heart failure No history of kidney disease No paralysis in the hand or arm No cancer recurrence

Exclusion criteria:

Age

From **47 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In present study, simple randomisation method is used. Using random number table, we selected first number randomly. If the selected number is between 0 and 5, we allocated the subject to intervention group (group A) and when the number is between 6 and 9, patients were allocated to control group (group B). This process was continued to recruit 30 patients.

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

Sport science Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2020-10-18, 1399/07/27

Ethics committee reference number

IR.SSRC.REC.1399.085

Health conditions studied

1

Description of health condition studied

Breast cancer related Lymphedema

ICD-10 code

I89.0

ICD-10 code description

Lymphedema, not elsewhere classified

Primary outcomes

1

Description

Quality of life

Timepoint

Three times: before study, after interventions and one month after treatment and exercise.

Method of measurement

Quality of life questionnaire; SF-36

2

Description

The expression of CA-153

Timepoint

48 hours before the intervention and at the end of the study

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

The edema volume

Timepoint

Three times: 48 hours before the intervention, at the end of the study and one month after the intervention

Method of measurement

Volumetric cylinder or volumetric tank or volumetric meter

2

Description

Shoulder range of motion

Timepoint

Three times: 48 hours before the intervention, at the end of the study and one month after the intervention

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group: The standard decongestant treatment method combined with selected pilates training was performed for 6 weeks and 5 days per week for 30-40 minutes. warm up exercises included 10 minutes of breathing exercises then the main movements were performed aiming at strengthening arm and shoulder muscles containing rest intervals, thus the exercises continued until fatigue which included 7 exercises in one to three sets for 20 minutes. At the end, stretching and body cooling exercises were performed for 5 minutes.

Category

Rehabilitation

2

Description

Control group: Patients in the control group received standard combined decongestive therapy involves manual drainage of lymph nodes which was performed daily (5 days a week) for 3 weeks for a total of 21 sessions. Each session consisted of 40 minutes of manual drainage of lymph nodes, performed by a trained therapist. Appropriate skin care methods were used, including moisturizing as well as using multi-layered short stretch bands. Baby oil was used as a lotion.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Lymphedema Clinic (private sector)

Full name of responsible person

Dr. Zahra Sheikhi

Street address

Unit 2, No. 1, Shariati St

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Tehran

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1941911371

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Dr.shaikhi88@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hassan Rasooli Saghai

Street address

Islamic Azad University, Tabriz Branch, Pasdaran Expressway, Tabriz, East Azerbaijan Province

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Tabriz

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Roghaye Mokhtari Hesari

Position

Non-faculty

Latest degree

Master

Other areas of specialty/work

Physiology

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After removing all variables related to identification of patients, the data would be shared. Patients has completed the consent from. data related to primary and secondary outcomes would be accessible.

When the data will become available and for how long

6 months after the publication of the first article in reputable journals, data will be available.

To whom data/document is available

The data will be provided to help researchers in their investigations as well as to inform patients about their condition

Under which criteria data/document could be used

Researchers can use the data of this study in their studies to conduct new studies. It will also be provided to patients in order to be aware of their condition.

From where data/document is obtainable

Roghayeh Mokhtari Hessari, PhD student in sports physiology Phone: 09145884100 Email r.hesari1353@gmail.com

What processes are involved for a request to access data/document

The request for data will be reviewed with the authors and contributors of the project and will be made available to others while maintaining ethical protocols. This process might take up to one month.

Comments