

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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)

##### Phone

+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  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1941911371  
**Phone**  
+98 21 7763 0356  
**Email**  
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  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5157944533  
**Phone**  
+98 41 3331 8681  
**Email**  
h\_rasooli@iaut.ac.ir  
**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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No. 30, Saadi 6, Andisheh

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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**