

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of 8 weeks of resistance training on some tumor markers, liver enzymes, quality of life and fatigue in metastatic breast cancer patients

Protocol summary

Study aim

Does 8 weeks of resistance training have an effect on tumor grafts, liver enzymes, improving quality of life and reducing fatigue in metastatic breast cancer patients?

Design

This study is in two control and training groups. The random sampling method is simple. The sample size is 28 people.

Settings and conduct

The purpose of this study is sports and it will be carried out in Naft Hospital in such a way that metastatic patients entered the plan after obtaining consent and performing a pretest which includes blood sampling and completing a questionnaire, 8 weeks of resistance training in the hospital's gym. Located on the top floor of the oncology department, it will be applied and then the post-test will also be done.

Participants/Inclusion and exclusion criteria

Women with metastatic breast cancer who are undergoing 30 cancer therapies, having metastases, being in the age range of up to 50 years, without fatty tissue, no activity during the last 6 months, the same treatment phase of the subjects, no medical prohibition to participate in Sports activities, absence of fracture and the possibility of its occurrence, absence of abnormalities limiting sports activities, absence of cardiovascular and musculoskeletal risk factors, absence of uncontrolled pain, more than one month of chemotherapy and radiotherapy, absence of Smoking and alcohol consumption.

Intervention groups

The intervention group will perform resistance training 3 times a week for 8 weeks and the control group will not receive any intervention during this period.

Main outcome variables

Tumor markers, Liver enzyme Quality of life, Fatigue.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200208046418N2**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **prospective**

Last update: **2023-05-27, 1402/03/06**

Update count: **0**

Registration date

2023-05-27, 1402/03/06

Registrant information

Name

somayeh nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3452 0750

Email address

s.f.nazari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-24, 1402/04/03

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 8 weeks of resistance training on some tumor markers, liver enzymes, quality of life and fatigue in metastatic breast cancer patients

Public title

The effect of exercise on metastatic breast cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Metastatic breast cancer patients undergoing hormone therapy in the last year
Absence of fatty liver
Inactivity in the last 6 months
Not having a medical prohibition to participate in sports activities
Absence of fracture and the possibility of its occurrence
Not having an abnormality limiting sports activity
Absence of cardiovascular and skeletal-muscular risk factors
Absence of uncontrolled pain
More than a month has passed since chemotherapy and radiotherapy

Exclusion criteria:

The presence of a fracture
Alcohol and smoking
Age less than 30 and more than 50
Patients who are in the treatment phase of chemotherapy or radiation therapy
Male patients

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of choosing a random sample is simple. In this method, first the list of names of all the members is written, then a score or number is assigned to each of them, and the required number is selected using a table of random numbers. Because the studied population is small, the lottery method is used, that is, the names of people are written on a paper and placed inside the box, then the papers are removed one by one until the desired sample size is complete.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This research consists of two training groups (intervention) and control (without intervention).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Razi University Research Ethics Committee

Street address

Razi University, University Street, Taq Bostan

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2023-05-04, 1402/02/14

Ethics committee reference number

IR.RAZI.REC.1402.010

Health conditions studied**1****Description of health condition studied**

Breast Cancer

ICD-10 code

C50.1

ICD-10 code description

Malignant neoplasm of central portion of breast

Primary outcomes**1****Description**

Tumor markers CEA, CA15-3

Timepoint

24 hours before the intervention and 24 hours after the last training session

Method of measurement

Taking blood samples

2**Description**

Liver enzymes ALT, AST and ALP

Timepoint

24 hours before the intervention and 24 hours after the last training session

Method of measurement

Taking blood samples

3**Description**

Quality of life

Timepoint

24 hours before the intervention and 24 hours after the last training session

Method of measurement

Questionnaire

4

Description

Fatigue

Timepoint

24 hours before the intervention and 24 hours after the last training session

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: resistance training (weight training), for 8 weeks, 3 times a week, 4 movements of the upper body and 4 movements of the lower body (based on the articles). At first, each person's 1RM is measured and the training intensity will be designed based on the person's initial power, the number of repetitions for each movement is 8 to 12 repetitions in 2 to 3 sets (all the above can be adjusted based on the person's power) all recommendations American College of Sports Medicine is considered for resistance training in breast cancer patients.

Category

N/A

2

Description

Control group: They do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Naft Hospital

Full name of responsible person

Behrooz Gharib

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Sarhang Sakhai St, Hafez St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Naft Hospital

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran Naft Hospital

Proportion provided by this source

99

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

Other

2

Sponsor

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Razi University of Kermanshah

Proportion provided by this source

1

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**

Razi University

Full name of responsible person

Somayeh Nazari

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Physiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the information obtained from this research project will be published as an article. Personal information of patients will remain confidential forever.

When the data will become available and for how long

Time of publication of articles

To whom data/document is available

All those for whom the information of this research

project can be useful.

Under which criteria data/document could be used

The research results can be made available to all interested parties.

From where data/document is obtainable

To the published articles of this research project.

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

Basically, raw data is not available to anyone, the results of the project can be obtained through articles.

Comments