Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Street address
Sarhang Sakhai St, Hafez St.
City
Tehran
Province
Tehran
Postal code
74114 11367
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Gharib.behrooz@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran Naft Hospital
Full name of responsible person
Behrooz Gharib
Street address
Sarhang Sakhai, Hafez Street
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Tehran
Postal code
11367-74114
Phone
+98 21 6670 0021
Email
Gharib.behrooz@yahoo.com
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
Razi University of Kermanshah
Street address
Razi University, University Street, Taq Bostan
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Postal code
6714414971
Phone
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Email
webmaster@razi.ac.ir
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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Person responsible for updating data

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Karaj
Province
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Postal code
3197937551
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Email
Somayeh.95.nazari@gmail.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
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