Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of 8 weeks of intermittent exercise and Ganoderma mushroom consumption on the structure and function of the heart of women undergoing chemotherapy with breast cancer

Protocol summary

Study aim

Determining the effect of 8 weeks of high-intensity interval training and Ganoderma capsule mushroom consumption on the structural and functional heart indices of women undergoing chemotherapy with breast cancer

Design

The research subjects will be women with breast cancer who are undergoing chemotherapy at Shahid Rahimi Hospital at the time of the research. So coordination and preliminary investigations with the oncology specialists of Shahid Rahimi Hospital of Khorram Abad will be called, in which the plan's status is explained. And the patients who meet the conditions of the research are invited to express their consent and participate in the research.

Settings and conduct

The samples of this research are 60 breast cancer patients of Shahid Rahimi Hospital in Khoram Abad city. They will be randomly divided into four groups: 1- Control group (15 people), 2- Ganoderma mushroom consumption group (15 people), 3- Aerobic exercise group (15 people), 4- Aerobic exercise group and Ganoderma mushroom consumption (15 people). 48 hours before and after the implementation of the research protocol, the structural and functional variables of the heart will be measured with an echocardiogram device.

Participants/Inclusion and exclusion criteria

1- No radiation therapy 2-Chemotherapy 3- Not performing any surgery 4- Not having any heart disease 5- Not consuming cigarettes and alcoholic beverages, 6- Blood pressure > 110/180 as criteria for exiting the study process, lack of continuous exercise before starting the training program, lack of metastasis 7-- Age range 35 to 55

Intervention groups

1- Control group 2- Ganoderma mushroom consumption group 3- Aerobic training group 4- Aerobic exercise group and consumption of Ganoderma mushroom

Main outcome variables

maximum oxygen consumption, ventricular wall, ventricular cavity, the size of the interventricular septum in the systole stage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230828059290N1**
Registration date: **2023-09-04, 1402/06/13**
Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**
Update count: **0**

Registration date

2023-09-04, 1402/06/13

Registrant information

Name

Fazlollah Fathollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3342 5492

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of 8 weeks of intermittent exercise and Ganoderma mushroom consumption on the structure and function of the heart of women undergoing chemotherapy with breast cancer

Public title
The effect of exercise and Ganoderma mushroom on breast cancer

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
No radiotherapy Chemotherapy No surgery Not having any heart disease Not consuming cigarettes and alcoholic beverages, not having physical problems such as orthopedic and brain-neural problems that prevent exercise, blood pressure > 110/180 as a criterion for exiting the study process, not having continuous exercise before starting the training program, not having metastases. Age range from 35 to 55

Exclusion criteria:
Reluctance to participate in the plan Having heart disease

Age
From **35 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this method, block randomization will be used. In order to perform block randomization, a specific code will be assigned to each of the people under study (60 people). Then, blocks with a volume of 8 people, which have 4 exclusive codes, are defined. Two A codes, two B codes, two C codes, and two D codes are defined. Each of these four codes represent each of the groups under study. From the combination and sequence of these codes in blocks of 8, different blocks are created. Then, using Stata software version 17 and using the command code egen block, blocks of 8 are selected by a simple random method with placement. Using a simple random method with placement, the number of 8 blocks is selected and considering that the sample size is equal to 60 people, half of the eighth block will be included in the study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Lorestan University of Medical Sciences Research Ethics Committees Certificate

Street address
st

City
khoramabad

Province
Lorestan

Postal code
1236547896

Approval date
2023-08-09, 1402/05/18

Ethics committee reference number
IR.LUMS.REC.1402.171

Health conditions studied

1

Description of health condition studied
breast cancer

ICD-10 code
C50.0

ICD-10 code description
Malignant neoplasm of nipple and areola

Primary outcomes

1

Description
The size of the left ventricular cavity at the end of diastole

Timepoint
48 hours before and after the last training session

Method of measurement
Eco cardiography

2

Description
The size of the left ventricular cavity at the end of systole

Timepoint
48 hours before and after the last training session

Method of measurement
Eco cardiography

3

Description
The size of the interventricular septum in the diastole phase
Timepoint
48 hours before and after the last training session
Method of measurement
Eco cardiography

4

Description
The size of the thickness of the dorsal free wall of the left ventricle
Timepoint
48 hours before and after the last training session
Method of measurement
Eco cardiography

5

Description
Left ventricular mass size
Timepoint
48 hours before and after the last training session
Method of measurement
Eco cardiography

Secondary outcomes

1

Description
Maximum oxygen consumption (VO2peak)
Timepoint
48 before and after the last training session
Method of measurement
Rockport walking test

2

Description
blood pressure
Timepoint
48 before and after the last training session
Method of measurement
Sphygmomanometer

Intervention groups

1

Description
Intervention group:Ganoderma mushroom consumption group will consume 1.6 grams of Ganoderma mushroom powder in capsule form daily for 8 weeks. Ganoderma capsules are prepared by the Faculty of Pharmacy of Lorestan University of Medical Sciences. In order to coordinate and check the effect of Ganoderma mushroom, Ganoderma capsules will be taken every day at 6 pm.
Category
Prevention

2

Description
Intervention group: Interval training:Intervention group: Intermittent training group: The subjects of the training group will perform three sessions of incremental aerobic exercise every week for eight weeks, the intensity of which will be determined according to the target heart rate. The target heart rate was calculated based on the Karonen method. The subjects will perform three training sessions a week under the supervision of two permanent experts. Based on the research and considering the age of the subjects, low to moderate intensity exercise will be used for these patients. Heart rate was measured using a polar heart rate monitor. The subjects of the exercise group will participate in the program for eight weeks and three sessions each week, each session lasting 60 minutes. The training protocol of the high-intensity interval group also included 4 intervals of 4 minutes with an intensity of 50-75% of the maximum heart rate and 3 minutes of active rest with an intensity of 50% of the maximum heart rate. The subjects of this group will start the exercise with the intensity of 60% of the maximum heart rate and gradually with the progress of the subjects' preparation, the intensity of the exercise will be increased by 5% every week.
Category
Prevention

3

Description
Intervention group: Intermittent training group + consumption of Ganoderma mushroom. This group will perform interval training three times a week for eight weeks and consume 1.6 grams of Ganoderma mushroom powder in capsule form daily for 8 weeks.
Category
Prevention

4

Description
Control group: Do not have any sports activities and Ganoderma mushroom consumption
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahimi Khorramabad Hospital
Full name of responsible person
Yahya Baharond of Iran

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Street, Azadi Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Bahram Rasoulian
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Kamalvand, 4 KM, Borujerd Road, Lorestan Medical Sciences Complex
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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
Khoram-Abad 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
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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
No - There is not 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
Participants' data is confidential
When the data will become available and for how long
The data will be provided to the participants after analysis
To whom data/document is available
Research team
Under which criteria data/document could be used
To publish as an article
From where data/document is obtainable
To the laboratory and the executive of the research project
What processes are involved for a request to access data/document
There is no special process
Comments