Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of a period of combined exercise training on tumor markers, blood glucose homeostasis, blood lipid, upper limb range of motion and quality of life among patients with diabetes type II after breast cancer surgery

Protocol summary

Study aim
Effect of a period of combined exercise training on tumor markers, blood glucose homeostasis and quality of life in patients with diabetes type 2 after breast cancer surgery among

Design
Randomized clinical trial with control group, non blinded, with parallel groups

Settings and conduct
Among type 2 diabetic patients after breast cancer surgery, thirty volunteer women will be selected as the study population and will randomly be divided into two experimental and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with type 2 diabetes after breast cancer surgery, Performing Chemotherapy and Radiation Therapy Exclusion criteria: Have any particular diet, and physical and mental problems that limit their participation in the training for example cardiovascular disease and cognitive disorders

Intervention groups
Experimental group: Combined exercises including aerobic training (at 50 to 75% of maximum heart rate) and resistance exercise (using elastic Bands) in each session, three sessions per week for 8 weeks. Control group: Without intervention

Main outcome variables
Cancer markers, blood glucose homeostasis, blood lipids, upper limb range of motion, shoulder pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150531022498N29**
Registration date: **2019-04-15, 1398/01/26**
Registration timing: **retrospective**

Last update: **2019-04-15, 1398/01/26**
Update count: **0**

Registration date
2019-04-15, 1398/01/26

Registrant information

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Ramin Shabani

Name of organization / entity
Islamic Azad University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-09, 1397/01/20

Expected recruitment end date
2018-07-22, 1397/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of a period of combined exercise training on tumor markers, blood glucose homeostasis, blood lipid, upper limb range of motion and quality of life among patients with diabetes type II after breast cancer surgery

Public title
Effect of a period of combined exercise training in patients with diabetes type II after breast cancer surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women with type 2 diabetes after breast cancer surgery Performing Chemotherapy and Radiation Therapy Not having exercise training
Exclusion criteria:
Having any particular diet Patients with psychiatric and nervous disorders who are being treated with sedative medicines Patients with orthopedic, verbal and auditory problems
Age
From **46 years** old to **67 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects were divided into 2 groups (one control group and 1 experimental groups) using the random numbers table
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
Ethics committee of Rasht Azad University
Street address
Rasht Branch، Islamic Azad University, Taleshan Bridge
City
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Province
Guilan
Postal code
4147654919
Approval date
2018-07-15, 1397/04/24
Ethics committee reference number
IR.IAU.RASHT.REC.1396.157

2

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4147654919
Approval date
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Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
CEA Plasma level
Timepoint
Before and after the end of 8weeks of training
Method of measurement
ELISA Kit

2

Description
CA15-3 Plasma level
Timepoint
Before and after the end of 8weeks of training
Method of measurement
ELISA Kit

3

Description
Fasting blood glucose
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

4

Description
Insulin resistance
Timepoint
Before and after the end of 8weeks of training
Method of measurement
ELISA Kit and HOMA-IR index

5

Description
Insulin
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

6

Description
shoulder pain
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using the MPQ Pain Questionnaire

7

Description
Range of motion of upper limb
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
goniometer

8

Description
Blood glucose
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

9

Description
Total Cholesterol
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

10

Description
Triglycerides
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

11

Description
High density lipoprotein
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

12

Description
low density lipoprotein
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

13

Description
HbA1c
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
ELISA Kit

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using the WHOQOL questionnaire

2

Description
Anxiety
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using the anxiety questionnaire

3

Description
physical fitness
Timepoint
Before and after the end of 8 weeks of training
Method of measurement
Using aerobic power measurement

4

Description
Body composition
Timepoint
Before and after the end of 8 weeks of training
Method of measurement

Measure waist circumference , height , weight, body fat percentage, body mass index using the In body device.

Intervention groups

1

Description
Intervention group: Eight weeks of concurrent resistance and aerobic exercises with 3 sessions per week will be done. Aerobic exercise including Ergometer, treadmills and aerobic with an intensity of 50 to 75% of maximum heart rate will be conducted. Resistance exercises are done using elastic Bands.
Category
Rehabilitation

2

Description
Control group: Without any intervention, subjects in this group will continue their normal routines during the 8-week study period.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Gilan Radiotion oncology clinic
Full name of responsible person
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Sponsors / Funding sources

1

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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
Rasht Branch, Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
En The study was not completed
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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