

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Name

Ramin Shabani

Name of organization / entity

Islamic Azad University

Country

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

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.IAU.RASHT.REC.1396.157

2**Ethics committee****Name of ethics committee**

Ethics committee of Rasht Azad University

Street address

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Postal code

4147654919

Approval date

2018-07-15, 1397/04/24

Ethics committee reference number

IR.IAU.RASHT.REC.1396.156

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 8 weeks 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

Dr Hamid Saeidi Saedi

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Shahid Ansari Avenu, Namaz Blvd, Golsar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht Branch, Islamic Azad University

Full name of responsible person

Ali Delpasand

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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

Rasht Branch, Islamic Azad University

Full name of responsible person

Maryam kolaei, Poursan Akbari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Azad University of Rasht Branch

Full name of responsible person

Dr. Ramin Shabani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data**Contact****Name of organization / entity**

Azad University of Rasht Branch

Full name of responsible person

Marzieh Nazari

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work**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