

# 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)

###### Phone

+98 13 3375 2715

###### Email address

shabani@iaurasht.ac.ir

##### 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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**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

##### Street address

Shahid Ansari Avenu, Namaz Blvd, Golsar

##### City

Rasht

##### Province

Guilan

##### Postal code

۴۱۴۷۶۵۴۹۱۹

##### Phone

+98 13 3375 9662

##### Email

maryamkoulaei@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht Branch, Islamic Azad University

##### Full name of responsible person

Ali Delpasand

##### Street address

Rasht Branch, Islamic Azad University, Taleshan Bridge

##### City

Rasht

#### Province

Guilan

#### Postal code

4147654919

#### Phone

+98 13 3342 2153

#### Email

shabani\_msn@yahoo.com

#### 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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##### Phone

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##### Email

Poursanakb@gmail.com

## 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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Physiology

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marzieh.nazari.v@gmail.com

**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