

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Exercise training effects on improving resistance to chemotherapy in patients with breast and gastrointestinal cancer: Randomize phase II clinical trail

#### Protocol summary

##### Summary

According to increased drug resistance and high prevalence of cancer, a lot of studies have been performed in developed countries for improving the quality of life and enhancing the survival rate in patient. Among these, attention to physical activity and exercise training have been very important and have attracted many advocates. Therefore, the present randomized trial study will be aimed to investigate the role of the interval exercise training on improving of the parameters involved in chemotherapy resistance in treatment-resistant breast and gastrointestinal cancer patients. Subjects include 60 female patients with breast and gastrointestinal cancer between the ages of 30 to 60 years, referred to Cancer Institute of Iran since September 2016 to September 2017 which randomly divides into two groups: the exercise training with standard treatment group and without the exercise training group. The exercise training duration is 13 weeks, and before the start of training protocol and 48 hours after the last exercise session. Serum samples from patients are collected before and after the exercise training and stored at -80 °C until measurement time. Evaluations include the Vo2 max measurement, the life quality survey, and assay to p-gp, ABC, P53, P63, P68, BRCA1 and BRCA2, topoisomerase I and II, Her2, and metallothionein, glutathione and superoxide dismutase using conventional ELISA, Western blot and immunohistochemistry methods.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041818745N7**

Registration date: **2016-06-30, 1395/04/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-30, 1395/04/10

##### Registrant information

###### Name

Ali Mohammad Alizadeh

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2501

###### Email address

aalizadeh@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Iran University of Medical Sciences and Golestan University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Exercise training effects on improving resistance to chemotherapy in patients with breast and gastrointestinal cancer: Randomize phase II clinical trail

##### Public title

Exercise training effects on improving resistance to chemotherapy in patients with breast and gastrointestinal

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria consist: 30-60 year-old women with breast and gastrointestinal cancers; detection of the disease during years 94 and 95; during chemotherapy; by obtaining written consent; lack of response to at least one chemotherapy period (treatment response less than 50%; local recurrence of the disease; the ability of doing exercise training. Exclusion criteria consist: the lack of cardiovascular disease; out of control blood pressure; diabetes; mental illness; infection or immune and endocrine diseases; metastatic disease.

### **Age**

From **30 years** old to **60 years** old

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Iran University of Medical Sciences

##### **Street address**

Tehran, Hemmat Highway, Iran University of Medical Sciences

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2015-06-22, 1394/04/01

#### **Ethics committee reference number**

IR.IUMS.REC.1394.25629

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Breast cancer

#### **ICD-10 code**

C50

#### **ICD-10 code description**

Malignant neoplasm of breast

### **2**

#### **Description of health condition studied**

colon cancer

#### **ICD-10 code**

C18

#### **ICD-10 code description**

Malignant neoplasm of colon

## **Primary outcomes**

### **1**

#### **Description**

Response to treatment

#### **Timepoint**

Destroy of tumor or decrease of tumor size

#### **Method of measurement**

CT or MRI

## **Secondary outcomes**

### **1**

#### **Description**

Vo2 max , quality of life , and p-gp, ABC, P53, P63, P68, BRCA1 and BRCA2, topoisomerase I and II, Her2, and metallothionein, glutathione and superoxide dismutase

#### **Timepoint**

before and after the exercise training

#### **Method of measurement**

Questionnaire- Patient records- Blood samples- Western blotting- ELISA- Immunohistochemistry- gene expression

## **Intervention groups**

### **1**

#### **Description**

2- The second group receives only the standard treatments.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

1- The first group receives exercise training with the standard treatments (13 weeks, 3 sessions per week, each session 60-90 min)

#### **Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Cancer Research Center, Cancer Institute of IR. Iran,  
Imam Khomeini Hospital

**Full name of responsible person**

Dr. Ali Mohammad Alizadeh

**Street address**

3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam  
Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

University In Tehran, Iran

**Full name of responsible person**

Dr. Mousavi

**Street address**

Fifth Floor, Iran University of Medical Sciences  
Hemmat Highway

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University In Tehran, Iran

**Proportion provided by this source**

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

2

### Sponsor

**Name of organization / entity**

Golestan University Of Medical Sciences

**Full name of responsible person**

Dr. Khosh Niyat

**Street address**

Central Organization of Golestan University of Medical  
Sciences, Iran Hyrkan, Gorgan, Golestan

**City**

Gorgan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Golestan University Of Medical Sciences

**Proportion provided by this source**

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Cancer Research Center, Cancer Institute of IR. Iran

**Full name of responsible person**

Dr. Ali Mohammad Alizadeh

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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

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**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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**City**

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**Postal code****Phone**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*