

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effect of Aerobic Training and Pomegranate Juice on micRNAs levels associated with Oxidant-Antioxidant Systems in Survivors of Breast Cancer

#### Protocol summary

##### Study aim

Investigate the effect of aerobic training with pomegranate juice consumption on the serum enzyme levels associated with the oxidant-antioxidant system of women rescued from breast cancer

##### Design

A Randomized, parallel group clinical trial design of 40 patients with non blinded outcome assessment

##### Settings and conduct

Obtain the necessary permissions; visits to specialised Oncology centers in Rasht County, including Razi, Arya and Golsar Hospitals. Prepared lists of women with Breast Cancer referred to the above centers in 2018 and 2019. Selection of 59 eligible people. The final readiness of 40 women and obtain their permission.

##### Participants/Inclusion and exclusion criteria

Entry requirements: women with Breast Cancer at the age range of 30 - 45 years old who have passed specific treatment courses like chemotherapy and radiation. Non-entry requirements: history of surgery, physiological menopause; using tobacco or alcohol; affected by systemic, cardiovascular, musculoskeletal, hormonal, immunological and mental disorders.

##### Intervention groups

Four equal groups of 10 member. Group1: Aerobic Exercise; group 2: the pomegranate juice; group 3: the Aerobic exercise and pomegranate Juice; group 4: the control group without exercise and pomegranate juice.

##### Main outcome variables

Malondialdehyde (MDA) levels; Superoxide Dismutase (SOD) levels ;Glutathione Peroxidase (GPX) levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200726048213N1**

Registration date: **2020-08-12, 1399/05/22**

Registration timing: **retrospective**

Last update: **2020-08-12, 1399/05/22**

Update count: **0**

##### Registration date

2020-08-12, 1399/05/22

##### Registrant information

###### Name

Babak rouzbehan

###### Name of organization / entity

Islamic Azad University of Rasht

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3334 5975

###### Email address

rouzbehan@iaurasht.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-23, 1398/09/02

##### Expected recruitment end date

2020-02-06, 1398/11/17

##### Actual recruitment start date

2019-12-07, 1398/09/16

##### Actual recruitment end date

2020-02-20, 1398/12/01

##### Trial completion date

2020-02-20, 1398/12/01

##### Scientific title

Effect of Aerobic Training and Pomegranate Juice on micRNAs levels associated with Oxidant-Antioxidant

**Public title**

Effect of Aerobic Training and Pomegranate Juice in Breast Cancer

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All Women with Breast Cancer The age range between 30 and 45 Completion of Treatment courses like Chemotherapy and Radiation

**Exclusion criteria:**

Physiological Menopause at the time of Cancer diagnosis The History of Specialized Treatment like Chemotherapy and Radiation in the last Six Months Performing Cancer-related Surgeries Chronic systematic disease, such as Diabetes and Hypertension Cardiovascular disease such as Heart Failure, Coronary Artery Disorders and severe Hypertension Hormonal abnormalities and immunity disorders Known Mental illness Tobacco and Alcohol use Problems, defects and disease of musculoskeletal system- preventative of Sport activity The history of ongoing Sports exercises before the study begins Cancer cells metastasis and involved of the other Body tissues and Organs

**Age**

From **30 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study, the simultaneous effects of aerobic training and Pomegranate juice consumption has been investigated on progression of Breast cancer by monitoring some of the microRNAs and oxidant agents associated with cancer

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Qom University

**Street address**

University of Qom, Alghadir Blvd., Qom, Iran

**City**

Qom

**Province**

Ghous

**Postal code**

3716146611

**Approval date**

2019-12-07, 1398/09/16

**Ethics committee reference number**

IR.QOM.REC.1399.001

**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**

The percentage of people with decrease in the level of mir-21

**Timepoint**

48 hours before the onset and 48 hours after the end of study

**Method of measurement**

Blood Test

**2**

**Description**

The percentage of people with decrease in the level of mir-155

**Timepoint**

48 hours before the onset and 48 hours after the end of study

**Method of measurement**

Blood Test

**3**

**Description**

The percentage of people with increase in the level of mir-34

**Timepoint**

48 hours before the onset and 48 hours after the end of study

**Method of measurement**

Blood Test

## Secondary outcomes

### 1

#### Description

Serum levels of oxidant factor; Malondialdehyde (MDA)

#### Timepoint

48 hours before the onset and 48 hours after the end of study

#### Method of measurement

Blood Test

### 2

#### Description

Serum levels of antioxidant factor; Glutathione Peroxidase (GPX)

#### Timepoint

48 hours before the onset and 48 hours after the end of study

#### Method of measurement

Blood Test

### 3

#### Description

Serum levels of antioxidant factor; Superoxide Dismutase (SOD)

#### Timepoint

48 hours before the onset and 48 hours after the end of study

#### Method of measurement

Blood Test

## Intervention groups

### 1

#### Description

Intervention group: aerobic exercise with Stationary Bike, 60 to 90 minutes, 3 sessions per week, for 8 weeks

#### Category

Prevention

### 2

#### Description

Intervention group: Natural pomegranate juice, 100 cc, fasting every morning, for 8 weeks

#### Category

Prevention

### 3

#### Description

Intervention group: aerobic exercise and pomegranate juice, 60 to 90 minutes of exercise, 3 sessions per week with pomegranate juice, 100 cc, fasting every morning, for 8 weeks

#### Category

Prevention

### 4

#### Description

Control group: Without exercise training and consumption of pomegranate juice

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi hospital

##### Full name of responsible person

Babak Rouzbehan

##### Street address

Sardar Jangal Ave., Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41448

##### Phone

+98 13 3354 1001

##### Fax

+98 13 3355 9787

##### Email

razi.hospital@yahoo.com

##### Web page address

<http://www.gums.ac.ir/razi>

### 2

#### Recruitment center

##### Name of recruitment center

Arya hospital

##### Full name of responsible person

Babak Rouzbehan

##### Street address

Alongside the Sardar Jangal international Air port, Anzali blvd., Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

33375 49790

##### Phone

+98 13 3375 9790

##### Fax

+98 13 3372 7203

##### Email

info@aryahospital.ir

##### Web page address

<http://www.aryahospital.ir>

### 3

#### Recruitment center

##### Name of recruitment center

Golsar hospital

**Full name of responsible person**

Babak Rouzbehan

**Street address**

142 Ave., Sommaye Blvd., Golsar, Rasht

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**Province**

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**Email**

info@golsarhospital.ir

**Web page address**

http://golsarhospital.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Islamic Azad University of Rasht branch

**Full name of responsible person**

Alireza Seidavi

**Street address**

Islamic Azad University of Rasht branch, Taleshan  
Bridge, Lakan blvd, Raht

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info@iaurasht.ac.ir

**Web page address**

http://iaurasht.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University of Rasht branch

**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**

Islamic Azad University of Rasht branch

**Full name of responsible person**

Babak Rouzbehan

**Position**

Faculty instructor, PHD student

**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University of Tehran Science and  
Research Branch

**Full name of responsible person**

Hossein Abed Natanzi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise Physiology

**Street address**

Science and Research Branch, Daneshgah Blvd,  
Simon Bulivar Blvd, Tehran

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**Province**

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**Postal code**

1477893855

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## Person responsible for updating data

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**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Exercise Physiology

**Street address**

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**Province**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available