Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Onchology centers in Rasht County, including Razi, Arya and Golsar Hospitals. Prepared lists of women with Breast Cancer referred to the above centers in 20118 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

Systems in Survivors of Breast Cancer

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 beween 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, Crononary Artery Disorders and severe Hypertension Hormonal abnormalities and immunity disorders Known Mental illness Tobacco and Alcohol use Problems, defects and disease of muscuskeletal system-preventative of Sport activity The history of ongoing Sports exercises before the study begins Cancer cells metastatis 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 airobic training and Pomegranate juice consumtion 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
Ghoum
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
City
Rasht
Province
Guilan
Postal code
4165763111
Phone
+98 13 3211 1718
Fax
+98 13 3211 1729
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
City
Rasht
Province
Guilan
Postal code
351641335
Phone
+98 13 3342 3153
Fax
+98 13 3344 7060
Email
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
Islamic Azad University of Rasht branch, Taleshan Bridge, Lakan blvd, Raht
City
Rasht
Province
Guilan
Postal code
351641335
Phone
+98 13 3342 3153
Email
rouzbehan@iaurasht.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1477893855
Phone
+98 21 4486 5154
Email
h-abednatanzy@srbiru.ac.ir

Person responsible for updating data

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
Islamic Azad University of Rasht branch, Taleshan Bridge, Lakan blvd, Raht
City
Rasht
Province
Guilan
Postal code
351641335
Phone
+98 13 3342 3153
Email
rouzbehan@iaurasht.ac.ir

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