

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of an aerobic exercise course on the associated serum microRNA levels with antiangiogenesis and cell death in prostate cancer patients

Protocol summary

Study aim

Investigation of eight weeks aerobic exercise effect on the associated serum microRNAs levels with antiangiogenesis and cell death in prostate cancer patients

Design

The clinical trial has an experimental group (n=10) and a control group (n=10) which it is voluntarily divided into two groups. The experimental group has no sports intervention and the control group do not have any intervention.

Settings and conduct

The list of men aged 55 to 66 years (Tehran city) were selected with benign prostate cancer without metastasis and the referred people to the centers in 1397. Necessary permits were obtained to refer to specialized oncology and urology treatment centers of Tehran University of Medical Sciences, including Shahid Hasheminejad and Sina Hospitals and related clinics. Out of 138 eligible people, 45 people had announced their readiness and finally, 20 people had the necessary conditions. And after obtaining their consents, they exercised with body weight and the above research was done in a sports club under the supervision of a researcher. Blinding has not been done.

Participants/Inclusion and exclusion criteria

Men aged 55 to 66 years old who have the benign cancer in Tehran city without metastasis and physical problems such as orthopedic and cerebral problems, neurological and also, interest in sports and participation in research projects

Intervention groups

Experimental group exercises are three sessions per week for 8 weeks and each training session includes 10 minutes of warm-up with a variety of stretching, flexibility and running and then, continuous running with a constant trend and intensity of 60 to 70% HRR. Also,

the control group does not have a regular exercise during these eight weeks and only has daily activities.

Main outcome variables

Serum microRNAs are associated with antiangiogenesis and cell death in prostate cancer patients including miR-15a, miR-16 and miR-329

General information

Reason for update

Acronym

TPCS

IRCT registration information

IRCT registration number: **IRCT20200928048866N1**

Registration date: **2020-10-29, 1399/08/08**

Registration timing: **retrospective**

Last update: **2020-10-29, 1399/08/08**

Update count: **0**

Registration date

2020-10-29, 1399/08/08

Registrant information

Name

Mehdi Garshasbi

Name of organization / entity

Social Security Organization

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 5503

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20
Expected recruitment end date
 2020-01-12, 1398/10/22
Actual recruitment start date
 2020-01-10, 1398/10/20
Actual recruitment end date
 2020-03-14, 1398/12/24
Trial completion date
 2020-03-14, 1398/12/24

Scientific title
 The effect of an aerobic exercise course on the associated serum microRNA levels with antiangiogenesis and cell death in prostate cancer patients

Public title
 Investigation of aerobic exercise effect on prostate cancer

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Obtaining the necessary permits for referring to specialized oncology treatment centers Failure to do the radiation therapy, chemotherapy and androgen therapy They have been diagnosed with prostate cancer at least one month ago Do not smoke or drink alcohol No physical problems that prevent exercise such as orthopedic, brain problems and nerve All patients with benign prostate cancer
Exclusion criteria:
 Blood pressure> 180/110 Cardiovascular diseases History of surgery Family dissatisfaction Overweight

Age
 From **55 years** old to **66 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **45**
 Actual sample size reached: **20**

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 effect of exercise activities on angiogenesis and anti-angiogenesis factors and microRNA changes has been investigated in cancer patients by monitoring some microRNAs and factors that increase the associated angiogenesis with cancer and it can cause metastasis and resistance to chemotherapy and other treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University

Street address

Unit 4, No. 22, , Banafsheh Alley, Jihad Akbar St., Sattari Highway Mojahed Kabir St., West Laleh Blvd

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Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.QOM.REC.1398.021

Health conditions studied

1

Description of health condition studied

The role of exercise and microRNAs in prostate cancer

ICD-10 code

C60-c63

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

The percentage of people with decreasing the serum mirRNA-15a

Timepoint

Pre and post-test

Method of measurement

Blood test (RNA extraction kit for Riz biofanavaran company. And also, RT steam-loop house keeping method was used to check microRNA levels)

Secondary outcomes

1

Description

The percentage of people with decreasing the serum mirRNA-329

Timepoint

Pre and post-test

Method of measurement

Blood test (RNA extraction kit rena biotechnology company. And also, RT steam-loop house keeping

method was used to check microRNA levels)

2

Description

The percentage of people with decreasing the serum mirRNA-16-1

Timepoint

Pre and post-test

Method of measurement

Blood test (RNA extraction kit rena biotechnology company. And also, RT steam-loop house keeping method was used to check microRNA levels)

Intervention groups

1

Description

Intervention group: Resistance training consisted includes eight weeks and 3 sessions per week. The program includes a 10-minute warm-up session with a various of stretching, flexibility and running exercises. Then, continuous running with a constant trend and intensity of 60 to 70% of HRR (Carvonen formula) was performed using a pulse gauge belt. The duration of running was 15 minutes in the first session and one minute was added to each session in the running time. The maximum heart rate was calculated from the formula age-220. At the end of each session, the cooling operation will be achieved by performing soft running, stretching and soft movements for ten minutes.

Category

Treatment - Other

2

Description

Control group: without treatment and participate in exercise. It plays important role in the experimental process

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad Hospital

Full name of responsible person

Mehdi garshasbi

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

no

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, University of Research
Sciences
Proportion provided by this source
100
Public or private sector
Public
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
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Mehdi garshasbi
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Person responsible for updating data

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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

Failure to complete information in this issue

Study Protocol

No - There is not 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