Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of eight weeks of aerobic exercise and pomegranate juice on some microRNAs and enzymes related to the oxidative / anti-oxidative system of men with prostate cancer

Protocol summary

Study aim

Simultaneous effect of pomegranate juice and aerobic exercise on people with prostate cancer

Design

The clinical trial consisted of three experimental groups and a control group of two phase 2 randomized blind patients on 60 patients. The experimental group includes aerobic exercise group, pomegranate juice consumption group, aerobic exercise group and control group. Pomegranate juice groups consumed pomegranate juice for eight weeks and 6 days each week.

Settings and conduct

The place of this research is in Lorestan province and Khorramabad city. To select the samples, first they will refer to specialized centers and urology offices and then the required samples will be selected according to the inclusion criteria. Study with non-random allocation And without blinding.

Participants/Inclusion and exclusion criteria

1- Do not perform radiation therapy, chemotherapy and androgen therapy 2- Do not perform any surgery 3- Not having any heart disease 4- Do not smoke or drink alcohol 5 - No physical problems such as orthopedic and cerebrovascular problems that prevent exercise. 6- Blood pressure> 110/180 as a criterion for leaving the study process 7- Lack of continuous exercise before starting the exercise program 8-> PSA 6 as a criterion for entering the study process

Intervention groups

In this study, 4 groups include three experimental groups and one control group. The experimental group includes aerobic exercise group, pomegranate juice consumption group, aerobic exercise group and control group. The pomegranate juice groups consumed pomegranate juice for eight weeks and 6 days each week, the aerobic exercise group consumed three sessions of aerobic exercise for 35 weeks and 35 minutes per week on a stationary bike for 75-60 minutes. Percentage of maximum heart rate will work.

Main outcome variables

microRNA-24,microRNA-34,microRNA-155

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200901048588N1**
Registration date: **2020-11-08, 1399/08/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-08, 1399/08/18**
Update count: **0**

Registration date

2020-11-08, 1399/08/18

Registrant information

Name

Mahnaz Mardani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3692 3548

Email address

f.fathollahi1984@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-11-22, 1399/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of eight weeks of aerobic exercise and pomegranate juice on some microRNAs and enzymes related to the oxidative / anti-oxidative system of men with prostate cancer

Public title

The effect of pomegranate juice and exercise on prostate cancer

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Failure to perform radiation therapy, chemotherapy and androgen therapy Do not perform any surgery > PSA 6 as a benchmark for the study process Lack of continuous exercise before starting the exercise program

Exclusion criteria:

Perform specialized treatments such as chemotherapy and radiation therapy in the last 6 months Perform prostate cancer related surgeries having cardiovascular disease, diabetes and neurological diseases Alcohol consumption, smoking Cancer cell metastasis and involvement of other tissues and organs in the body

Age

From **45 years** old to **60 years** old

Gender

Male

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Lorestan University of Medical Sciences

Street address

Khorramabad 5 km Boroujerd road

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2020-10-07, 1399/07/16

Ethics committee reference number

IR.LUMS.REC.1399.195

Health conditions studied

1

Description of health condition studied

prostate cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

microRNA-21,microRNA-34,microRNA-155

Timepoint

48 hours before and after eight weeks of aerobic exercise and consumption of pomegranate juice

Method of measurement

Real time-PCR device

Secondary outcomes

1

Description

Prostate-Specific Antigen (PSA),Superoxide dismutase(SOD),Glutathione peroxidase(GPX),Malondialdehyde(MDA)

Timepoint

48 hours before and after the performance, eight weeks of aerobic training and consumption of pomegranate juice

Method of measurement

ELISA device

Intervention groups

1

Description

Intervention group: Aerobic exercise with a work bike, 60 to 90 minutes, 3 sessions per week, for 8 weeks

Category

Prevention

2

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

3

Description
Natural pomegranate juice, 100 cc, every morning fasting, for 8 weeks
Category
Prevention

4

Description
Control group: No aerobic exercise and consumption of pomegranate juice
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
مطب های مربوط متخصصین ارولوژی
Full name of responsible person
مهناز مردانی
Street address
West Goldasht, School of Health and Nutrition
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msmardani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mahnaz Mardani
Street address
Khorramabad 5 km of Boroujerd road
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Email
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Grant name
Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences
Grant code / Reference number
1588-99-1-1397
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Mahnaz Mardani
Position
Professor of Lorestan University of Medical Sciences, Dean of the Faculty of Health and Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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

No - There is not 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