

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Eight-Week Concurrent Training on Expression of P53 and P21 Tumor Suppressor Genes in Men with Prostate Cancer

Protocol summary

Study aim

The Illumination of The Effect of Eight-Week Concurrent Training on Expression of P53 and P21 Tumor Suppressor Genes in Men with Prostate Cancer.

Design

this research is a clinical trial that the subjects were compared to experimental and control groups and randomly divided into two groups of 10 control and experimental groups without Blinding.

Settings and conduct

This research can be done by referring to the pathology department of Baqiyatallah El - Azam Subspeciality Hospital and reviewing the medical records of men with prostate cancer.

Participants/Inclusion and exclusion criteria

The entering criteria for the study include: Physical health based on a medical history questionnaire, no smoking and no participation in any training's program at least 2 months before take part In the training's program of this research and subjects after the cardiovascular's examination, blood pressure measurements and electrocardiogram recording by a specialist, getting to permit a log in the plan and get informed consent form in this research by the subjects. Exclusion criteria include: Not attending more than 3 sessions, having heart disease or pulmonary disease, and change in the health status that prevents physical activity.

Intervention groups

The control group will continue to carry out regular daily activities. Experimental group subjects included the exercise protocol: concurrent training course (aerobic-resistance) that designed by the researcher, for three days a week for 8 weeks. Resistance training at 60-75% intensity of one repetition maximal and aerobic exercise at 60-75% maximum heart rate will be done.

Main outcome variables

aerobic capacity: p53: p21

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037667N1**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Mohammad Asghari rekabdarkolaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4321 7126

Email address

asghari.moh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Eight-Week Concurrent Training on Expression of P53 and P21 Tumor Suppressor Genes in Men with Prostate Cancer

Public title

The Effect of Eight-Week Concurrent Training on Expression of Tumor Suppressor Genes in Men with Prostate Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects are putted at the stage T1 and T2 of the disease and are treated under the same way. The entering criteria for the study include: Physical health based on a medical history questionnaire that has no history of cardiovascular disease, high blood pressure, diabetes, renal disease, no smoking or participation in any exercise program at least 2 months before take part in Exercise Training program Subjects get allowed to enter the project after a cardiovascular examination, blood pressure measurement and ECG monitoring by a specialist. Take The Physical activities readiness questionnaire (PAR-Q) and The informed consent form for participation in this research by subjects.

Exclusion criteria:

Not attending more than 3 sessions having of heart or lung disease Change in health that prevent physical activity

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

Randomized

Randomization description

due to the health status and acceptance of the patients to the testing stages, use the selection method the maximum sample in the Morgan table, 20 men aged 51-75 years old and BMI of 23-29 kg / m2 randomly divided in to two groups of 10 Control unit and experimental.

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.SBMU.RETECH.REC1396.819

Health conditions studied

1

Description of health condition studied

prostate cancer

ICD-10 code

D07.5

ICD-10 code description

Carcinoma in situ of prostate

Primary outcomes

1

Description

P53 tumor suppressor protein

Timepoint

Before the intervention and the end of the intervention

Method of measurement

Blood samples will be collected 24 hours before the training starts and 48 hours after the last exercise session.

2

Description

P21 tumor suppressor protein

Timepoint

Before the intervention and the end of the intervention

Method of measurement

Blood samples will be collected 24 hours before the training starts and 48 hours after the last exercise session.

3

Description

Aerobic capacity

Timepoint

Before the intervention and the end of the intervention

Method of measurement

To estimate the maximum oxygen consumption, the Modified Bruce test on the treadmill [based on the maximum oxygen consumption equation: $8.545 + (\text{test run time} \times 2.282)$]

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Experimental group with practice protocol contain a concurrent training course (aerobic-resistance) that designed by the researcher (according to the American College of Medicine-Sports) for three days a week for 8 weeks. The Concurrent training program combines endurance training and resistance training that runs in two equal time steps which includes 55 minutes of training in the first and second weeks to 70 minutes in the seventh and eighth weeks. Warm up for 10 minutes Then Resistance training program included four movements of upper and lower large muscle groups that will be excuted three session per week with a severity of 60 to 75%, one repetition maximum, and for two time with 10 repetitions and three-minute break between turns. The beginning of the course with 60% of maximal repetition that increases by five percent every two weeks. Aerobic exercise with 15 minutes of activity with 60% heart rate maximum, starting at three sessions per week, which is performed with resistance training in one session. [based on the maximum heart rate equation: $[(220 - \text{years}) \pm 10]$. Starting The course with 60% maximum heart rate will be added every two weeks 5% to this amount and Five minutes to period. At the end of each exercise session, 10 minutes recovery to original state and cool down (slow running, walking and tensile movements for recovery) will be done.

Category

Rehabilitation

2

Description

Control group: The control group will continue to perform its daily activities and was requested to no participate in exercise training during this period.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah El - Azam Subspeciality Hospital

Full name of responsible person

Kambiz Hasrak

Street address

Baqiyatallah El-Azam Subspeciality Hospital, Sheikh Bahai Av, Mulla Sadra St, Vanak Sq, Tehran

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dr_hasrak@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza barari

Street address

Islamic Azad University Ayatollah Amoli Branch, University feeder, old road Amol to Babol 5 km, Amol

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4635143358

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Alireza54.barari@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Full name of responsible person

mohammad asghari rekabdarkolaee

Position

Ph.D Student of Exercise Physiology

Latest degree

Master

Other areas of specialty/work

Physiology

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza barari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad asghari rekabdarkolaee

Position

Ph.D Student of Exercise Physiology

Latest degree

Master

Other areas of specialty/work

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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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available