

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Impact of concurrent (aerobic-resistance) training on serum levels of IGF-I and IGFBP-3 in men with prostate cancer

Protocol summary

Study aim

The Impact of concurrent (aerobic-resistance) training on serum levels of IGF-BP3, IGF-1-, PTEN and SHBG in men with prostate cancer

Design

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

Settings and conduct

In Baqiyatallah University of Medical Sciences twenty men with prostate cancer randomly will be divided as control and training groups. Training group will perform eight weeks concurrent training . At the beginning and the end of the period, blood samples will be taken in dose of 5 ml to measure serum levels of IGF-I and IGFBP-3.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Subjects are putted at the stage T1 and T2 of the disease . The entering criteria for the study include: Physical health based on a medical history questionnaire. no participation in any training's program at least 2 month 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 long in the plan and get informed consent form in this research by the subjects. Exclusion criteria include:having heart disease or pulmonary disease, high blood pressure, diabetes, renal disease and smoking .

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

PTEN, IGF-1, IGFBP-3, SHBG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180624040222N1**

Registration date: **2018-11-11, 1397/08/20**

Registration timing: **retrospective**

Last update: **2018-11-11, 1397/08/20**

Update count: **0**

Registration date

2018-11-11, 1397/08/20

Registrant information

Name

Abbas Jafari

Name of organization / entity

Payame Noor University

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 5399

Email address

abbast_jafari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The Impact of concurrent (aerobic-resistance) training on serum levels of IGF-I and IGFBP-3 in men with prostate cancer

Public title
The Impact of concurrent (aerobic-resistance) training on prostate cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Subjects are putted at the stage T1 and T2 of the disease . Physical health based on a medical history questionnaire that has no history of disease. No participation in any exercise program atleast 2 month 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:
Having of heart or lung disease. Having high blood pressure. Having diabetes Having renal disease smoking

Age
From **50 years** old to **75 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

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. based on sortition, odd and even numbers were selected for experimental and control groups, respectively.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2016-08-01, 1395/05/11

Ethics committee reference number

IR.BMSU.REC.1395.17

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

Phosphatase and tensin homolog (PTEN)

Timepoint

Before the intervention (Before the 8 week concurrent (aerobic-resistance) training) and the end intervention(after the 8 week concurrent (aerobic-resistance) training).

Method of measurement

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

2

Description

Insulin-like growth factor 1 (IGF-1)

Timepoint

Before the intervention (Before the 8 week concurrent (aerobic-resistance) training) and the end intervention(after the 8 week concurrent (aerobic-resistance) training).

Method of measurement

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

3

Description

Insulin-like growth factor-binding protein 3

Timepoint

Before the intervention (Before the 8 week concurrent (aerobic-resistance) training) and the end intervention(after the 8 week concurrent (aerobic-resistance) training).

Method of measurement

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

4

Description

Sex hormone-binding globulin (SHBG)

Timepoint

Before the intervention (Before the 8 week concurrent (aerobic-resistance) training) and the end intervention(after the 8 week concurrent (aerobic-resistance) training).

Method of measurement

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

5

Description

Aerobic capacity

Timepoint

Before the intervention (Before the 8 week concurrent (aerobic-resistance) training) and the end intervention(after the 8 week concurrent (aerobic-resistance) training).

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: Intervention group with practice protocol contain a concurrent training course (aerobic-resistance) that designed by the researcher(according to the American College of Sports Medicine) 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 minute then resistance training program included four movements of upper and lower large muscle groups that will be executed 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 repetitions that increases by five percent every two weeks. Aerobic training with 15 minutes of activity with 60% heart rate maximum, starting at three session per week, which is performed with resistance training in one session.[based on the maximum heart rate will be added every two weeks 5% to this a amount and five minute to period. at the end of each exercise session , 10 minute 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 carry out regular daily activities and there was no intervention in them.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah El- Azam Subspeciality Hospital

Full name of responsible person

Kambiz Hesrak.

Street address

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

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Email

P_Ghdian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholam Hossein Alishiri

Street address

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

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Alireza Ghadian

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hamid arazi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Person responsible for updating data

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Position

PhD Student of Exercise Physiology

Latest degree

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Other areas of specialty/work

Exercise Physiology

Street address

University of Guilan, Postal Code 4199613776, Khalij Fars highway (5th km of Ghazvin road).

City

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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