Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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 atlast 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 EI- 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

DO7.5

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 +(test run time × 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 bye 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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1435915371
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+98 21 8805 0435
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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 EI- 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

University of Guilan

Full name of responsible person

Hamid arazi

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Person responsible for updating data

Contact

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Abbas jafari

Position

PhD Student of Exercise Physiology

Latest degree

Master

Other areas of specialty/work

Exercise Physiology

Street address

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

City

Rasht

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Guilan

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abbast_jafari@yahoo.com

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