Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of high-intensity interval training(HIIT) and quercetin supplementation on oxidative stress, level of concentric pathologic hypertrophy and cardiac function in patients with hypertension and CAD after PCI.

Protocol summary

Study aim
the effect of high-intensity interval training(HIIT) and quercetin supplementation on oxidative stress and level of concentric pathologic hypertrophy in patients with hypertension and CAD after PCI.

Design
A concealed, randomized, blinded, sham controlled clinical trial with a parallel group

Settings and conduct
In this semi experimental randomized, placebo-controlled and double-blind study, 36 men with hypertension and CAD after PCI aged 40-60 years, randomly divided into 3 groups of HIIT+quercetin(n=12), HIIT+placebo(n=12) and quercetin(n=12) were followed for 8 weeks of HIIT (30 seconds of activity and 30 seconds of rest) and quercetin consumption (250 mgr of quercetin supplement or placebo pills daily). Echocardiography was used to investigate morphological factors such as PWd and LVEDd. The TAC and MDA were measured by ELISA method. Data were analyzed using paired-sample T-test and ANOVA.

Participants/Inclusion and exclusion criteria
men with hypertension and CAD after PCI

Intervention groups
HIIT+quercetin(n=12), HIIT+placebo(n=12) and quercetin

Main outcome variables
MDA , TAC ,EF, LVEDd, PWd

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160927030023N3**
Registration date: **2020-02-20, 1398/12/01**
Registration timing: **retrospective**

Last update: **2020-02-20, 1398/12/01**
Update count: **0**

Registration date
2020-02-20, 1398/12/01

Registrant information

Name
Khalilullah Moonikh

Name of organization / entity
Rajai Teacher Training University

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
2018-12-22, 1397/10/01

Actual recruitment end date
2019-03-21, 1398/01/01

Trial completion date
2019-09-29, 1398/07/07

Scientific title
The effect of high-intensity interval training(HIIT) and quercetin supplementation on oxidative stress, level of concentric pathologic hypertrophy and cardiac function

in patients with hypertension and CAD after PCI.

Public title
The effect of high-intensity interval training(HIIT) and quercetin supplementation on oxidative stress, level of concentric pathologic hypertrophy and cardiac function

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least 2 and up to 4 weeks after angioplasty (drug stent only), Male 40-60 years old Systolic hypertension (SBP <130 mmHg <130) Mild to moderate congenital cardiac hypertrophy

Exclusion criteria:
Patients' non-adherence to exercise protocol Exercise outside the rehabilitation center Non-compliance with supplement use (less than 80% or less than 1 day) Changing health and abnormal change of medication People who have a history of kidney failure, heart attack or heart valve surgery, have aortic stenosis, dilated cardiomyopathy, and EF below 30%, are in frequent practice of PVC or AF. Leaving practice sessions over 1 week or more than 3 dispersed sessions

Age
From **40 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **36**
Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research simple randomization method is used. The participants will be divided into 3 groups of 12 people. For this purpose, from 1 to 3 each number is written 12 numbers on the paper and participants are asked to assign a number to each of them and group them according to their number.

Blinding (investigator's opinion)
Double blinded

Blinding description
Prior to the study, supplement and placebo cans were marked by a person other than the researcher to inform the researcher and subjects of the type of capsules received. Supplement and placebo were administered under the same supervision.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sport Sciences Research Institue of IRAN

Street address
NO 3, 5th alley, Miremad Ave, Tehran

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Tehran

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Postal code
1587958711

Approval date
2019-03-19, 1397/12/28

Ethics committee reference number
IR.SSRI.REC.1397.373

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

2

Description of health condition studied
CAD

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
MDA

Timepoint
Before and after 8 weeks

Method of measurement
Elisa

2

Description
TAC

Timepoint
Before and after 8 weeks

Method of measurement

Elisa

3

Description
LVEDd
Timepoint
Before and after 8 weeks
Method of measurement
Eco cardiography

4

Description
PWDd
Timepoint
Before and after 8 weeks
Method of measurement
Eco cardiography

5

Description
EF
Timepoint
Before and after 8 weeks
Method of measurement
Eco cardiography

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Before and after 8 weeks
Method of measurement
Manometer

2

Description
Diastolic blood pressure
Timepoint
Before and after 8 weeks
Method of measurement
Manometer

Intervention groups

1

Description
Intervention group: 250 mg doses of 1 capsules of quercetin+ HIIT for 8 weeks
Category
Rehabilitation

2

Description
Control group: 2 + placebo control group resistance training for 8 weeks
Category
Rehabilitation

3

Description
Intervention group: Quercetin supplement group, 1 capsule 250 mg daily quercetin
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahman Hospital Heart Rehabilitation Center
Full name of responsible person
Khalil Mamoodi
Street address
Rajai Teacher Training University, St.Shabanlo, Lavizan, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Rajaee Teacher Training University
Full name of responsible person
Majid Kashef
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Rajai Teacher Training University, St.Shabanlo Lavizan, Tehran
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Grant name
Research Credits
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Rajaee Teacher Training University

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

Rajai Teacher Training University

Full name of responsible person

Khalil Ullah Moonikh

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Position

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Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable