Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of four weeks endurance training and MitoQ supplementation alone and in combination on serum level of some of microRNAs effective on blood pressure and oxidant, antioxidant, inflammatory and on functional cardiac factors in hypertensive patients

Protocol summary

Study aim
Evaluation of the effect of four weeks endurance training and MitoQ supplementation on serum level of some of microRNAs effective on blood pressure and oxidant, antioxidant, inflammatory and on functional cardiac factors in hypertensive patients

Design
The study is parallel and two-blind (researcher and subject) and the allocation of patients to the intervention and control group is randomly simple. (6 groups; n = 60)

Settings and conduct
In a Shafa hospital with a cardiologist, bicycle and blood tests and echo can be done. The researcher and the subject both are unaware of the interventions

Participants/Inclusion and exclusion criteria
Participants and entry criteria: Men 40 to 55 years of age with systolic blood pressure equal to or greater than 140 mm Hg and diastolic blood pressure equal to or greater than 90 mm Hg. Exit criteria: Liver, kidney, lung, diabetes, certain diseases such as cancer and other cardiovascular diseases

Intervention groups
1) Hypertension (HTN) control: Systolic blood pressure equal to or greater than 140 and diastolic blood pressure equal to or greater than 90 mm Hg 2) HTN with endurance exercise: People with HTN have bicycle endurance training for 4 weeks (3 times a week). 3) HTN with MitoQ Supplement: People with HTN receive a capsule of MitoQ supplemental (20 mg per day for 4 weeks). 4) HTN with placebo: People with HTN receive a placebo capsule MitoQ orally for 4 weeks a day. 5) HTN with MitoQ supplementation and endurance training: Hypertensive individuals undergo a cycling endurance training (3 times per week for 4 weeks), during which time Daily receive one MitoQ orally (20 mg/day). 6) HTN with oral administration of placebo and endurance training: Similar to group 5. They will only receive a placebo instead of a supplement.

Main outcome variables
miR21, 27a, 126, 222 and oxidant, antioxidant, inflammatory factors and on functional cardiac factors (Echo)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190228042870N1**
Registration date: **2019-04-17, 1398/01/28**
Registration timing: **prospective**

Last update: **2019-04-17, 1398/01/28**
Update count: **0**

Registration date
2019-04-17, 1398/01/28

Registrant information

Name
Hamid Najafipour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of four weeks endurance training and MitoQ supplementation alone and in combination on serum level of some of microRNAs effective on blood pressure and oxidant, antioxidant, inflammatory and on functional cardiac factors in hypertensive patients

Public title

Evaluation the effect of endurance training and MitoQ supplementation on blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

systolic blood pressure > 140 mmHg Diastolic pressure > 90 mmHg

Exclusion criteria:

Liver, kidney, lung, diabetes diseases and certain diseases like cancer

Age

From **40 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants randomly and on the basis of throwing dice into separate groups to compare different treatments by researchers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and all study personnel were blinded to treatment assignment and lipid measurements. Treatments that take place on the participants are impartial and it is not clear which treatment is the best when it comes to clinical testing.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Kerman University of Medical Sciences

Street address

Jihad Bolvd.Ebnsina Ave.Kerman,Iran

City

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Province

Kerman

Postal code

7619813159

Approval date

2019-03-17, 1397/12/26

Ethics committee reference number

IR.KMU.REC.1397.595

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

110-115

ICD-10 code description

Hypertensive diseases

Primary outcomes

1

Description

miR-21

Timepoint

At the beginning of the study (before the intervention) and 28 days after taking the MitoQ supplement or performing endurance training

Method of measurement

Real-Time PCR

2

Description

miR-27a

Timepoint

At the beginning of the study (before the intervention) and 28 days after taking the MitoQ supplement or performing endurance training

Method of measurement

Real-Time PCR

3

Description
miR-126
Timepoint
At the beginning of the study (before the intervention) and 28 days after taking the MitoQ supplement or performing endurance training
Method of measurement
Real-Time PCR

4

Description
miR-222
Timepoint
At the beginning of the study (before the intervention) and 28 days after taking the MitoQ supplement or performing endurance training
Method of measurement
Real-Time PCR

5

Description
Blood pressure
Timepoint
before the intervention and Days 1, 3, 5, ... and 28th day
Method of measurement
Sphygmomanometer

6

Description
Percentage of arterial oxygen saturation
Timepoint
Before training, during training, immediately after training and at intervals of 15, 30 and 45 minutes after training
Method of measurement
Pulse Oximeter

7

Description
HDL-c
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

8

Description
Oxidized LDL
Timepoint
before the intervention and 28th day
Method of measurement
Elisa kit

9

Description
Cholestrol
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

10

Description
Triglyceride
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

11

Description
Heart rate
Timepoint
Before training, during training, immediately after training and at intervals of 15, 30 and 45 minutes after training
Method of measurement
Pulse Oximeter

12

Description
Left Ventricular End-Systolic Diamater
Timepoint
before the intervention and 28th day
Method of measurement
Echocardiography

13

Description
Left Ventricular End-diastolic Diamater
Timepoint
before the intervention and 28th day
Method of measurement
Echocardiography

14

Description
Ejection Fraction
Timepoint
before the intervention and 28th day
Method of measurement
Echocardiography

15

Description
Shortening Fraction
Timepoint
before the intervention and 28th day
Method of measurement
Echocardiography

16

Description
superoxide dismutase
Timepoint
before the intervention and 28th day
Method of measurement
Elisa kit

17

Description
Glutathione Peroxidase
Timepoint
before the intervention and 28th day
Method of measurement
Elisa kit

18

Description
Malondialdehyde
Timepoint
before the intervention and 28th day
Method of measurement
Elisa kit

19

Description
Interleukin-6
Timepoint
before the intervention and 28th day
Method of measurement
Elisa kit

20

Description
Hs-CRP
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

21

Description
Creatinine
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

22

Description
Alanine aminotransferase (SGPT)
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

23

Description
Aspartate aminotransferase (SGOT)
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

24

Description
Alkaline Phosphatase
Timepoint
before the intervention and Days 14 and 28
Method of measurement
Biochemical autoanalyzer

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Hypertension: People in this study have a systolic blood pressure equal to or greater than 140 mm Hg and a diastolic blood pressure equal to or greater than 90 mm Hg. During the study period, which lasted for 4 weeks, no intervention was performed on They do not accept.
Category
Diagnosis

2

Description
Intervention group: 1); Hypertension group with endurance training: In this group, people with hypertension for 4 weeks (3 times a week), exercise endurance bike with specified strength and depending on the aerobic capacity.
Category
Rehabilitation

3

Description
Intervention group: 2) Hypertension group with MitoQ supplemented oral administration: In this group, people with hypertension receive a supplement of oral MitoQ capsules at a dose of 20 mg/day for 4 weeks a day. MitoQ is a mitochondria-targeted antioxidant(Advanced CoQ10 Formula). MitoQ is produced by MitoQ company (Auckland, New Zealand).
Category
Treatment - Drugs

4

Description

Intervention group: 3) Hypertension group with oral administration of placebo: In this group, people with hypertension receive a placebo capsule of MitoQ daily for 4 weeks a day.

Category

Treatment - Drugs

5

Description

Intervention group: 4) Hypertension group with MitoQ supplement supplementation and endurance training: In this group, people with hypertension have a cycling endurance training for 4 weeks in 3 times per week, and at the same time they receive a daily MitoQ capsule of 20 mg per day. MitoQ is a mitochondria-targeted antioxidant(Advanced CoQ10 Formula). MitoQ is produced by MitoQ company (Auckland, New Zealand).

Category

Treatment - Drugs

6

Description

Intervention group: 5) The group was in hypertension with oral administration of placebo (placebo) and endurance training: In this group, people with hypertension have a cycling endurance training for 4 weeks in 3 times per week, and they receive a single placebo capsule of MitoQ daily for oral administration.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Hospital
Full name of responsible person
Hamidreza Nasri
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http://www.kmu.ac.ir/fa/sh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Yaser Masoumi-Ardakani
Position
Researcher
Latest degree
Master
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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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
Not applicable

Title and more details about the data/document
Post-publication results will be available as an article to everyone. All data will also be available to the Physiology Research Center

When the data will become available and for how long
Since 1400

To whom data/document is available
Physiology Research Center of Kerman University of Medical Sciences, patients and other researchers

Under which criteria data/document could be used
There is no limit

From where data/document is obtainable
Physiology Research Center of Kerman University of Medical Sciences

What processes are involved for a request to access data/document
Attendance at the center or written request from other universities

Comments