

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 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

##### Country

Iran (Islamic Republic of)

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+98 34 3223 6839

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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

kerman

##### 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**

Cholesterol

### **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 Diameter

**Timepoint**

before the intervention and 28th day

**Method of measurement**

Echocardiography

### 13

**Description**

Left Ventricular End-diastolic Diameter

**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

**Street address**

Shafa street, Shafa Hospital

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kpr@kmu.ac.ir

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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**

Dr Abbas pardakhti

**Street address**

Deputy of research and technology, Jahad Blvd, Ebne sina street

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abpardakhty@kmu.ac.ir

**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**

Physiology

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## Person responsible for scientific inquiries

### Contact

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**Latest degree**

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## Person responsible for updating data

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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**