

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The effect of Resveratrol supplement on metabolic profiles and genes expression of Sirtuin-1, TNF- α , TGF- β , IL-1, PPAR γ in diabetetic coronary artery disease patients

Protocol summary

Study aim

The aim of this study is to determine the effects of Resveratrol supplementation on metabolic profiles and genes expression of Sirtuin-1, TNF- α , TGF- β , IL-1, PPAR γ in diabetetic coronary artery disease patients

Design

Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: Among patients with CHD referred to Naghavi outpatient Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

patients with T2DM, aged 40-85 years old with proven 2- and 3-vessel CHD will be included in this study. Exclusion criteria: consuming resveratrol three months prior to the intervention, taking antioxidant and/or anti-inflammatory supplements such as vitamin E and vitamin C, having an acute myocardial infarction or cardiac surgery in the past three months, or having renal or hepatic failure

Intervention groups

Patients will be assigned into two groups to receive Resveratrol supplement (n=30) or placebo (n=30). Resveratrol and placebo capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 4 weeks after the intervention. At the beginning and end of the intervention: 4 weeks.

Main outcome variables

Insulin resistance (primary outcomes) and biomarkers of inflammation and oxidative stress factors, FPG, insulin, QUICKI, serum lipids, IL-1, PPAR- γ , TNF- α , TGF- β , SIRT1 (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181029041490N1**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **retrospective**

Last update: **2019-09-04, 1398/06/13**

Update count: **1**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Asma Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5533 8702

Email address

hosseini-as@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-16, 1397/05/25

Expected recruitment end date

2018-09-16, 1397/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Resveratrol supplement on metabolic profiles and genes expression of Sirtuin-1, TNF- α , TGF- β , IL-1, PPAR γ in diabetic coronary artery disease patients

Public title

Effect of supplementation in treatment of Coronary Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with T2DM, aged 40-85 years old with proven 2- and 3-vessel CHD

Exclusion criteria:

Consuming resveratrol three months prior to the intervention Taking antioxidant and/or anti-inflammatory supplements such as vitamin E and vitamin C Having an acute myocardial infarction or cardiac surgery in the past three months Having renal or hepatic failure

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with balanced randomization method and random numbers generated by computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants, researchers, data collectors, evaluators and data analyzers are not aware of which group is placebo or supplemented.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2018-08-13, 1397/05/22

Ethics committee reference number

IR.Kaums.MEDNT.REC.1397.41

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description

Insulin resistance

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

hs-CRP

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Elisa kit

2

Description

Total antioxidant

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Gene expression of sirtuin1

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Real Time PCR

6

Description

Gene expression of interleukin-1(IL-1)

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Real Time PCR

7

Description

Gene expression of tumor necrosis factor alpha (TNF- α)

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Real Time PCR

8

Description

Gene expression of transforming growth factor beta (TGF- β)

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Real Time PCR

9

Description

Gene expression of peroxisome proliferator-activated receptor gamma (PPAR- γ)

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Real Time PCR

10

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

11

Description

Insulin

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Elisa kit

12

Description

Triglycerides

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

13

Description

VLDL-cholesterol

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

14

Description

Total cholesterol

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

15

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

16

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Enzymatic kit

17

Description

Quantitative insulin sensitivity check index(QUICKI)

Timepoint

At the beginning of the study and after 4 weeks of intervention

Method of measurement

Calculation using standard formula

Intervention groups

1

Description

Intervention group: Resveratrol supplements, 500mg, daily, for 4 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo, daily, for 4 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi outpatient Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaee Avenue, Kashan

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8713743444

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naghavihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan 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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Gholamreza Namazi

Position

Academic staff member of the Department of Clinical Biochemistry

Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available