Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Resveratrol supplement on metabolic profiles and genes expression of Sirtuin-1، TNF-α، TGF-β، IL-1، PPARγ 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 profilesand and genes expression of Sirtuin-1 ،TNF-α، TGF-β، IL-1، PPARγ 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 (secondry 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، PPARγ in diabetetic 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
Isfehan

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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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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
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