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
  City
    Kashan
  Province
    Isfehan
  Postal code
    8713743444
  Phone
    +98 31 5545 0031
  Email

naghavihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
  Name of organization / entity
    Kashan University of Medical Sciences
  Full name of responsible person
    Gholamali Hamidi
  Street address
    Ghotbe Ravandi Boulevard, Kashan
  City
    Kashan
  Province
    Isfehan
  Postal code
    8715988141
  Phone
    +98 31 5554 0021
  Email
    research@kaums.ac.ir
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
    Ph.D.
  Other areas of specialty/work
    Biochemistry
  Street address
    Ghotbe Ravandi Boulevard, Kashan
  City
    Kashan
  Province
    Isfehan

Postal code
8715988141
Phone
+98 31 5554 0021
Email
namazimajid@gmail.com

Person responsible for scientific 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
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 0021
Email
namazimajid@gmail.com

Person responsible for updating data

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
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 0021
Email
namazimajid@gmail.com

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