Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of Resveratrol on plasma and peripheral blood mononuclear cells (PBMCs) oxidative stress factors of type 2 diabetic patients

Protocol summary

Summary

Resveratrol, one of the phytochemicals with anti-oxidant activity, has a high potential in treatment of type 2 diabetes. The aim of this study is to investigate the effect of resveratrol on plasma and peripheral mono-nuclear cells (PBMCs) oxidative stress of the diabetic patients in a double-blind randomized clinical trial. Sixty patients with type 2 diabetes were divided into two groups randomly (30, having resveratrol, 500 mg, twice daily, morning and evening for 60 days). The 2nd group (30 patients) receives the same amount of the placebo. All patients will receive routine medication for diabetes during the study. The lack of life-threatening diseases such as cancer, infectious diseases, cardiovascular and liver diseases are of the inclusion criteria for this study. At the first and the end of the study, blood sample are taken to measure the levels of glucose, HbA1c, lipid profile, plasma oxidative stress markers such as total anti-oxidant capacity, malondialdehyde, protein carbonyl, advanced glycation end products. Furthermore, peripheral blood mononuclear cells (PBMCs) oxidative stress will be evaluated by measurement of reactive oxygen species (ROS), glutathione and the expression of SIRT1 and MnSOD and RAGE.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072523336N1**
Registration date: **2015-08-19, 1394/05/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name
Reza Meshkani

Name of organization / entity
Department of Biochemistry, Faculty of Medicine, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research,Tehran University of Medical Sciences, Dr. Masoud Younesian. Diabetes Research Center, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Resveratrol on plasma and peripheral blood mononuclear cells (PBMCs) oxidative stress factors of type 2 diabetic patients

Public title

The effect of resveratrol on diabetes treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ability to give informed consent; Age 40-60 years; Diabetic patients with BMI less than 35 kg/m2; Lack of insulin therapy; HbA1c > 7.5. Exclusion criteria: Subjects on any antioxidant medication; Patient on non-steroidal anti-inflammatory drug; Patients on insulin therapy; Patients with severe diabetic complications such as nephropathy , retinopathy and amputation; On any agent with significant antioxidant properties; History of alcohol abuse; Any life threatening disease such as cancer and infectious diseases; Allergy to peanuts, grapes, wine, mulberries; Pregnant women; Coronary event or procedure (myocardial infarction, unstable angina, coronary artery bypass surgery or coronary angioplasty) in the previous four weeks; Subjects on anticoagulants; History of recent taking red grapes, pistachios, almonds and berries; ALT and/or AST > 2 times above upper limit of normal.

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Poursina avenue,

City
Tehran

Postal code

Approval date
2015-07-20, 1394/04/29

Ethics committee reference number
IR.TUMS.REC.1394.389

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
HbA1c

Timepoint
Before and two months after intervention

Method of measurement
HPLC

2

Description
FBS

Timepoint
Before and two months after intervention

Method of measurement
Enzymatic reaction

3

Description
Reactive oxygen species (ROS)

Timepoint
Before and two months after intervention

Method of measurement
Flow cytometry

Secondary outcomes

1

Description
HDL

Timepoint
Before and two months after intervention

Method of measurement
Spectrophotometry

2

Description
LDL

Timepoint
Before and two months after intervention

Method of measurement
Spectrophotometry

3

Description
Insulin
Timepoint
Before and two months after intervention
Method of measurement
ELISA Kit

4

Description
Cholesterol
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

5

Description
Triglyceride
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

6

Description
ALT
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

7

Description
AST
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

8

Description
Insulin resistance
Timepoint
Before and two months after intervention
Method of measurement
HOMA-IR

9

Description
CRP
Timepoint
Before and two months after intervention
Method of measurement
ELISA Kit

10

Description
Creatinine
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

11

Description
Urea
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

12

Description
BMI
Timepoint
Before and two months after intervention
Method of measurement
the formula for BMI is weight in kilograms divided by height in meters squared

13

Description
Diastolic and systolic blood pressure
Timepoint
Before and two months after intervention
Method of measurement
Sphygmomanometer and Stethoscope will be used to measure the blood pressure

14

Description
Glutathione
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

15

Description
Malondialdehyde (MDA)
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

16

Description
Plasma protein carbonyl
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

17

Description
Total antioxidant capacity
Timepoint
Before and two months after intervention
Method of measurement
Spectrophotometry

18

Description
Expression of Sirt1
Timepoint
Before and two months after intervention
Method of measurement
Real-time PCR

19

Description
Expression of MnSOD
Timepoint
Before and two months after intervention
Method of measurement
Real-time PCR

20

Description
Expression of RAGE
Timepoint
Before and two months after intervention
Method of measurement
Real-time PCR

Intervention groups

1

Description
Resveratrol, 500 mg, twice daily, morning and evening for 60 days
Category
Treatment - Drugs

2

Description
Placebo, 500 mg, twice daily, morning and evening for 60 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Research Center, Endocrinology and Metabolism Research Institute
Full name of responsible person
Dr Ensi Nasli Esfahani
Street address
Clinic of Diabetes, West 17 Shahrivar, North Kargar Ave, Amir Abad
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Younesian
Street address
Deptartment of Biochemistry, Faculty of Medicine, Tehran University of Medical Sciences, Poursina avenue
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Research, Tehran University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Diabetes Research Center, Endocrinology and Metabolism research Institute, Tehran University of Medi
Full name of responsible person
Dr. Ensi Nasli Esfahani
Street address
Clinic of Diabetes, No 17, West Shahrivar, North Kargar Avenue, Amir Abad, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Diabetes Research Center, Endocrinology and Metabolism research Institute, Tehran University of Medi

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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PhD Student of Clinical Biochemistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty