

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 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

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Tehran University of Medical Sciences

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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

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Department 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

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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

Shadi Seyyed Ebrahimi

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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