

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of resveratrol on plasma and peripheral blood mononuclear cells (PBMCs) inflammatory factors of patients with type 2 diabetes

Protocol summary

Summary

Resveratrol, one of the phytochemicals with anti-inflammatory activity, has a high potential in treatment of type 2 diabetes. The aim of this study is to investigate the effects of resveratrol on plasma and peripheral blood mononuclear cells (PBMCs) inflammatory factors in patients with type 2 diabetes 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 inflammatory factors, cytokine secretion capacity of peripheral blood mononuclear cells (PBMCs) and frequency of CD14+ and CD16+ circulating monocytes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080223336N2**

Registration date: **2015-09-02, 1394/06/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-02, 1394/06/11

Registrant information

Name

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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 effect of resveratrol on plasma and peripheral blood mononuclear cells (PBMCs) inflammatory factors of patients with type 2 diabetes

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

2015-07-25, 1394/05/03

Ethics committee reference number

IR.TUMS.REC.1394.424

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

Percent of CD14+ و CD16+ cells

Timepoint

Before and after two months of intervention

Method of measurement

Flow cytometry

2

Description

FBS

Timepoint

Before and after two months of intervention

Method of measurement

Enzymatic reaction

3

Description

HbA1c

Timepoint

Before and after two months of intervention

Method of measurement

HPLC

Secondary outcomes

1

Description

LDL

Timepoint

Before and after two months of intervention

Method of measurement

Spectrophotometry

2

Description

HDL

Timepoint

Before and after two months of intervention

Method of measurement

Spectrophotometry

3

Description

TG

Timepoint

Before and after two months of intervention
Method of measurement
Spectrophotometry

4

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

5

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

6

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

7

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

8

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

9

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

10

Description
BMI
Timepoint
Before and after two months of intervention

Method of measurement
Body weight(Kg)/height(m²)

11

Description
Systolic and diastolic blood pressure
Timepoint
Before and after two months of intervention
Method of measurement
Mercury sphygmomanometer

12

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

13

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

14

Description
TNF-α
Timepoint
Before and after two months of intervention
Method of measurement
ELISA

15

Description
IL-6
Timepoint
Before and after two months of intervention
Method of measurement
ELISA

16

Description
MCP-1
Timepoint
Before and after two months of intervention
Method of measurement
ELISA

17

Description
IL-10
Timepoint
Before and after two months of intervention
Method of measurement

18**Description**

Expression of SIRT1

Timepoint

Before and after two months of intervention

Method of measurement

Real-time PCR

19**Description**

Expression of TLR2

Timepoint

Before and after two months of intervention

Method of measurement

Real-time PCR

20**Description**

Expression of TLR4

Timepoint

Before and after two months of 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**

Clinic of Diabetes, Diabetes Research Center, Endocrinology and Metabolism Research Institute

Full name of responsible person

Dr Ensi Nasli Esfahani

Street address

Clinic of Diabetes, West Shahrivar, North Kargar Ave, Amir Abad, Tehran

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Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor of Research, Tehran University of Medical Sciences, Dr. Masoud Younesian

Full name of responsible person

Dr. Reza Meshkani

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Dept of Biochemistry, Faculty of Medicine, Tehran University of Medicine, 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, Dr. Masoud Younesian

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

Full name of responsible person

Dr. Ensi Nasli Esfahani

Street address

Clinic of Diabetes, West 17 Shahrivar, North Kargar, 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

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

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Person responsible for general inquiries

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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