Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Reza Meshkani

Name of organization / entity

Department of Biochemistry, Faculty of Medicine, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 3004

Email address

rmeshkani@sina.tums.ac.ir

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 nstitute, 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-a

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

ELISA

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
City
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
Street address
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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hadi Khodabandehloo
Position
Ph.D student of Clinical Biochemistry
Other areas of specialty/work
Street address
Tehran University of Medical Sciences, Poursina avenue
City
Tehran
Postal code
Phone
+98 21 8895 3004
Fax
Email
h.khodabandehloo@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Reza Meshkani
Position
PhD, Clinical Biochemistry
Other areas of specialty/work
Street address
Tehran University of Medical Sciences, Poursina avenue
City
Tehran
Postal code
Phone
+98 21 8895 3004
Fax
Email
rmeshkani@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hadi Khodabandehloo
Position
Ph.D student of Clinical Biochemistry
Other areas of specialty/work
Street address
Tehran University of Medical Sciences, Poursina avenue,
City
Tehran
Postal code
Phone
+98 21 8895 3004
Fax
Email
h.khodabandehloo@gmail.com
Web page address

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