

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of resveratrol on lipid and glycemic profile indices, expression of PPAR α , some factors associated with cell cycle arrest and sCD163 to sTWEAK ration in T2DM patients.

Protocol summary

Study aim

Effects of resveratrol on lipid and glycemic profile indices, expression of PPAR α , some factors associated with cell cycle arrest and sCD163 to sTWEAK ration in T2DM patients.

Design

A double blind controlled randomized parallel clinical Trial, will be performed on patients with type 2 diabetes. 72 patients will be randomly assigned to groups receiving resveratrol and the placebo group.

Settings and conduct

The present study will be conducted in a double blind randomized controlled trial. Participants and researchers will not be aware of the supplemental and placebo content. After giving a complete explanation about how the study is done, blood sampling and obtaining informed consent form, a demographic questionnaire will be completed at the beginning of the study. The diet, the level of physical activity, and body composition will be examined using standard methods at the beginning and end of the study. The mRNA expression levels for PPAR α , p53, p21 and p16 genes will be assessed using real-time polymerase chain reaction (PCR) and serum CD163 and TWEAK levels will be measured using commercially available ELISA kits at baseline and the end of the study.

Participants/Inclusion and exclusion criteria

Male and female with type 2 diabetes mellitus, aged 30-60 years with a body mass index of 24-30 kg/m² will be included in the study. Individuals with special conditions (pregnant, lactating, addicted, with other diseases and insulin use) will not be included in the study.

Intervention groups

The intervention and control group will be received capsules containing resveratrol (at a dose of 1000 mg/day) and methyl cellulose (at a dose of 1000 mg / day) respectively, for 8 weeks.

Main outcome variables

Expression values of p16, p21, p53 and PPAR α genes; serum levels of sCD163; serum levels of sTWEAK.

General information

Reason for update

The secondary outcome castelli 2 index was modified in term of linguistic adaptation.

Acronym

IRCT registration information

IRCT registration number: **IRCT20171118037528N1**
Registration date: **2017-12-29, 1396/10/08**
Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**

Update count: **4**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

shima abdollahi

Name of organization / entity

shahid sadoughi university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 353820910014

Email address

sh-abdollahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

shahid sadoughi University of Medical Sciences

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of resveratrol on lipid and glycemic profile indices, expression of PPAR α , some factors associated with cell cycle arrest and sCD163 to sTWEAK ratio in T2DM patients.

Public title

Effect of resveratrol on vascular function

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female subjects with established T2DM, who have been diagnosed for at least three months who have body mass index between 24-30 kgm², and aged 30-60 years,

Exclusion criteria:

clinical diagnosis of any liver, kidney, cancer and Alzheimer's diseases insulin therapy; HbA1c \geq 8% consumption of any antioxidant supplements in the last six months history of allergic reaction to grapes; consumption of anticoagulants, fibrates and aspirin drinking red wine and alcohol history of myocardial infraction presence of stent or battery in the heart gastrointestinal ulcer pregnancy or lactation; follow the unusual diet until one month before the study; unwillingness to participation in study

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified blocked randomization method will be used based on sex (male and female) and age (30-45 years and 45-60 years). To assign individuals to the intervention and control groups, a random number table will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Supplements and placebos will be provided in the same appearance and shape and they will be packed in the same bottles, and the only difference will be the letters

(A and B) on the bottles. Labels will be affixed to the bottles by someone who is not related to the study. Each bottle contains 120 capsules (for one-month usage). Participants and administrators will be unaware about the contents in the bottles.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Science

Street address

Safaeiye Ave., Alam Square., Shahid Sadoughi University of Medical Science., Yazd.

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

ir.ssu.sph.rec.1396.120

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Proximosome proliferator activated receptor alpha

Timepoint

Before and after intervention

Method of measurement

Gene expression

2**Description**

p53 gene
Timepoint
Before and after intervention
Method of measurement
Gene expression

3
Description
p21 gene
Timepoint
Before and after intervention
Method of measurement
Gene expression

4
Description
p16 gene
Timepoint
Before and after intervention
Method of measurement
Gene expression

5
Description
Soluble Cluster of Differentiation 163
Timepoint
Before and after intervention
Method of measurement
Serum concentration using kit and The enzyme-linked immunosorbent assay method

6
Description
TNF-related weak inducer of apoptosis
Timepoint
Before and after intervention
Method of measurement
Serum concentration using kit and The enzyme-linked immunosorbent assay method

7
Description
Paraoxonase1 activity
Timepoint
Before and after intervention
Method of measurement
Serum concentration using kit and The enzyme-linked immunosorbent assay method

8
Description
Asymmetric de-methyl arginine
Timepoint
Before and after intervention
Method of measurement
Serum concentration using kit and The enzyme-linked immunosorbent assay method

Secondary outcomes

1
Description
Total Triglyceride
Timepoint
Before and after intervention
Method of measurement
Turbidometry

2
Description
Total cholesterol
Timepoint
Before and after intervention
Method of measurement
Turbidometry

3
Description
High density lipoprotein Cholesterol
Timepoint
Before and after intervention
Method of measurement
Turbidometry

4
Description
Low density lipoprotein Cholesterol
Timepoint
Before and after intervention
Method of measurement
Turbidometry

5
Description
Fasting blood glucose
Timepoint
Before and after intervention
Method of measurement
Turbidometry

6
Description
Glycated hemoglobin
Timepoint
Before and after intervention
Method of measurement
Enzymatic kit

7
Description
Fasting insulin
Timepoint
Before and after intervention
Method of measurement

The enzyme-linked immunosorbent assay

8

Description

Lipid Accumulation Product

Timepoint

Before and after intervention

Method of measurement

Formula

9

Description

Visceral adiposity index

Timepoint

Before and after intervention

Method of measurement

Formula

10

Description

Castelli 1 index

Timepoint

Before and after intervention

Method of measurement

Formula

11

Description

Castelli 2 index

Timepoint

Before and after intervention

Method of measurement

Formula

12

Description

Atherogenic Coefficient

Timepoint

Before and after intervention

Method of measurement

Formula

Intervention groups

1

Description

Patients in the intervention group will receive two capsules of 500 milligrams of resveratrol per day in 8 weeks.

Category

Prevention

2

Description

Patients in the control group will receive two capsules of 500 milligrams of methyl cellulose per day in 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center and Clinics

Full name of responsible person

Shima abdollahi

Street address

Shahid Sadoughi Blvd., Diabetes Research Center and Clinics., Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity
Iran National Science Foundation
Full name of responsible person
Nosrat-o-allah Zargham
Street address
No. 33, Fifth Ave., North Karegar Ave., Tehran.
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Email
medicine@insf.org

Grant name

Grant code / Reference number

۹۶۰۱۰۶۶۰

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source

Iran National Science Foundation

Proportion provided by this source

50

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Shima Abdollahi
Position
Student
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I have not yet decided on this.

When the data will become available and for how long

I have not yet decided on this.

To whom data/document is available

I have not yet decided on this.

Under which criteria data/document could be used

I have not yet decided on this.

From where data/document is obtainable

I have not yet decided on this.

What processes are involved for a request to access data/document

I have not yet decided on this.

Comments