

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of resveratrol on lipid and glycemic profile indices, expression of PPAR $\alpha$ , 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 $\alpha$ , 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 $\alpha$ , 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/m<sup>2</sup> 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 $\alpha$  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 $\alpha$ , 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 kgm<sup>2</sup>, 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 proliferatore 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

##### **City**

Yazd

##### **Province**

Yazd

##### **Postal code**

8915173160

##### **Phone**

+98 35 3728 0228

##### **Email**

drc@ssu.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Research Associate, School of Public Health

##### **Street address**

Shohadaye gomnam Blvd., Campus of Shahid Sadoughi University of Medical Sciences Yazd., School of Public Health

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+98 35 3820 9100

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sphealth@ssu.ac.ir

#### **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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Tehran  
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1439634665  
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+98 21 8216 1159  
**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**  
Master  
**Other areas of specialty/work**  
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**Person responsible for scientific inquiries**

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**Person responsible for updating data**

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**Web page address**

## 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**