Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Public title
Effect of resveratrolon 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≥ 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
Proxisome 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
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3820 9100
Email
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.
City
Tehran
Province
Tehran
Postal code
1439634665
Phone
+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
Ṡhima Abdollahi
Position
Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Safaeiye Ave., Alam Square., Shahid Sadoughi University of Medical Science
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2241
Fax
Email
sh-abdollahi@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Hassan Mozaffari Khosravi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Safaeiye Ave., Alam Square., Public Health faculty., Shahid Sadoughi University of Medical Science
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 3149 2241
Fax
Email
mozaffari.kh@gmail.com
Web page address

Person responsible for updating data

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
Nutrition
Street address
No 13., Moein Ave., Pounak
City
Tehran
Province
Tehran
Postal code

8915173160

Phone

+98 21 4482 9552

Fax

Email

sh.abd6864@yahoo.com

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