

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effects of resveratrol supplementation on serum irisin and adiponectin in patients with type 2 diabetes

#### Protocol summary

##### Summary

**Objectives:** To determine effects of resveratrol on serum irisin and adiponectin in patients with type 2 diabetes.  
**Design:** Randomized double-blind placebo-controlled clinical trial. **Participants:** Patients with type 2 diabetes with BMI more than 25. **Setting and conduct:** Fifty five eligible patients with type 2 diabetes will be referred from Institute of Endocrinology and Metabolism, Firoozgar Hospital. They will be randomly assigned into two groups to receive daily either 240 mg resveratrol or placebo for 8 weeks. 10 cc fasting venous blood samples will be obtained at the beginning and the end of intervention and serum irisin and adiponectin will be measured by ELISA. In order to control confounding factors, height, weight, body fat and muscle percent, food intakes, physical activity, age, sex, FBS, insulin, HbA1c and medications will be assessed before and after intervention. **Intervention:** 240 mg resveratrol or placebo. **Main outcome measures:** serum irisin and adiponectin.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201601022394N19**  
Registration date: **2016-07-24, 1395/05/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-07-24, 1395/05/03

##### Registrant information

###### Name

Shima Jazayeri

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8670 4805

###### Email address

sjazayeri@razi.tums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Iran University of Medical Sciences

###### Expected recruitment start date

2015-06-22, 1394/04/01

###### Expected recruitment end date

2016-09-20, 1395/06/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effects of resveratrol supplementation on serum irisin and adiponectin in patients with type 2 diabetes

###### Public title

Effect of resveratrol on serum irisin and adiponectin in patients With type 2 diabetes

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of type 2 Diabetes for at least 2 years; willing to participate; BMI more than 25; age between 45 to 70 years old. Exclusion criteria: Significant diseases including cardiovascular, renal and liver diseases, or cancer; pregnancy; lactation; insulin use; weight and BMI change; consumption of nutritional supplements within the past 8 weeks.

###### Age

From **45 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **56**

**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**

Ethic committe of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmet Highway, Tehran, Iran

**City**

Tehran

**Postal code**

**Approval date**

2015-09-25, 1394/07/03

**Ethics committee reference number**

IR.IUMS.REC.1394.26168

**Health conditions studied**

1

**Description of health condition studied**

Type 2 Diabetes Mellitus

**ICD-10 code**

E11

**ICD-10 code description**

non-insulin-dependent-diabetes-mellitus

**Primary outcomes**

1

**Description**

Irisin

**Timepoint**

At baseline and after 8 weeks

**Method of measurement**

ELISA

2

**Description**

Adiponectin

**Timepoint**

At beaseline and after 8 weeks

**Method of measurement**

ELISA

**Secondary outcomes**

1

**Description**

Fasting Blood Sugar (FBS)

**Timepoint**

At baseline and after 8 weeks

**Method of measurement**

Biochemical assessment

2

**Description**

HbA1C

**Timepoint**

At baseline and after 8 weeks

**Method of measurement**

Biochemical assessment

3

**Description**

Insulin

**Timepoint**

At baseline and after 8 weeks

**Method of measurement**

ELISA

**Intervention groups**

1

**Description**

Resveratrol- 240 mg/day with lunch for 8 weeks

**Category**

Treatment - Other

2

**Description**

Placebo- 240 mg/day with lunch for 8 weeks

**Category**

Placebo

**Recruitment centers**

## 1

### Recruitment center

#### Name of recruitment center

Institute of Endocrinology and Metabolism, Firouzgar Hospital, Iran University of Medical Sciences

#### Full name of responsible person

Zahra Khajehpour

#### Street address

#### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

#### Full name of responsible person

Dr. Seyed Ali Javad Moosavi

#### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

#### 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 for research, Iran University of Medical Sciences

#### Proportion provided by this source

100

#### 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

Department of Nutrition, School of Public Health, Iran University of Medical Sciences.

#### Full name of responsible person

Zahra Khajehpour

#### Position

MSc Student of Nutrition

#### Other areas of specialty/work

#### Street address

Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran.

#### City

Tehran

#### Postal code

#### Phone

+98 21 8862 2806

#### Fax

#### Email

zahra.khajehpour@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Department of Nutrition, School of Public Health, Iran University of Medical Sciences

#### Full name of responsible person

Dr. Shima Jazayeri

#### Position

MD, PhD.

#### Other areas of specialty/work

#### Street address

Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran.

#### City

Tehran

#### Postal code

#### Phone

+98 21 8670 4805

#### Fax

#### Email

jazayeri.sh@iums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Department of Nutrition, School of public Health, Iran University of Medical Sciences

#### Full name of responsible person

Zahra Khajehpour

#### Position

MSc Student of Nutrition

#### Other areas of specialty/work

#### Street address

Department of Nutrition, School of Public Health, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran.

#### City

#### Postal code

#### Phone

00

#### Fax

#### Email

zahra.khajehpour@yahoo.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*