

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effects of Grape Seed Extract supplementation on insulin resistance , the serum biochemical markers, adiponectin and resistin in adolescents with metabolic syndrome

#### Protocol summary

##### Summary

The aim of this study is to determine effects of grape seed extract supplementation on insulin resistance , the serum biochemical markers, adiponectin and resistin in adolescents with metabolic syndrome. In this randomized double-blind study ,44 adolescents (13-19 years old ) with metabolic syndrome who do not use anti-inflammatory and antioxidant supplements and have no cardiovascular disease or any other interfering diseases, will be randomly allocated in supplement or placebo groups. The supplement group will receive 100 mg of grape seed extract capsules and the placebo group receive placebo capsules in a daily manner for 8 weeks. Demographic, 24-h food recall and international physical activity questionnaires will be completed for the subjects . At baseline, for all adolescents, nutritional and physical activity advice will be presented and they will be asked to follow the advice during the study. Anthropometric ( weight, height and waist circumference ) and biochemical measurements ( lipid profile, fasting blood glucose , insulin , adiponectin and resistin ) as well as blood pressure determination will be at the beginning and also after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013112611288N7**  
Registration date: **2016-02-04, 1394/11/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-04, 1394/11/15

##### Registrant information

###### Name

Mohammad Alizadeh

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7313

###### Email address

mdalizadeh@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Nutrition Research Center, Tabriz University of Medical

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of Grape Seed Extract supplementation on insulin resistance , the serum biochemical markers, adiponectin and resistin in adolescents with metabolic syndrome

##### Public title

The effects of Grape Seed Extract in adolescents with Metabolic Syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Adolescents aged 13-19 years; waist circumference (WC) above the 90th percentile in adolescents under 16 years old and WC more than 95 centimeter in adolescents over 16 years old plus 2 or more of the following items; HDL<40 mg/dL ( In teenage girls over 16 years old: HDL<50 mg/dL ) ; TG ≥ 150mg/dL; Fasting blood glucose ≥ 100 mg/dL; Systolic blood pressure ≥ 130 mmHg; Diastolic blood pressure ≥ 85mmHg Exclusion criteria: Suffering from heart disease ; Kidney disease ; Liver disease ; Hyperthyroidism or hypothyroidism; The use of anti-inflammatory drugs; smoking; Triglycerides above 500 mg per deciliter; Pregnancy in teenage girls ; The use of antioxidant supplements in the past three months; The use anticoagulant drugs , including aspirin , warfarin; Sensitivity to grapes

**Age**

From **12 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

**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**

Faculty of Nutrition, Tabriz University of Medical Sciences, Tabriz

**Street address**

Daneshgah Street, Tabriz University of Medical Sciences Tabriz

**City**

Tabriz

**Postal code****Approval date**

2015-11-23, 1394/09/02

**Ethics committee reference number**

TBZMED.REC.1394.771

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

Metabolic Syndrome

**ICD-10 code**

R73.9

**ICD-10 code description**

Hyperglycaemia, unspecified

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

Lipid profile (LDL, HDL, TG)

**Timepoint**

Before intervention and 8 weeks after intervention

**Method of measurement**

Enzymatic methods and Friedewald formula

**2****Description**

Fasting Blood Glucose

**Timepoint**

Before intervention and 8 weeks after intervention

**Method of measurement**

Measurement of fasting blood glucose by using kits

**3****Description**

HbA1c

**Timepoint**

Before intervention and 8 weeks after intervention

**Method of measurement**

Using ion exchange chromatography

**4****Description**

Fasting Plasma Insulin

**Timepoint**

Before intervention and 8 weeks after intervention

**Method of measurement**

Elisa

**5****Description**

Anthropometric Indices (weight , height, waist circumference , BMI)

**Timepoint**

Before intervention and 8 weeks after intervention

**Method of measurement**

Using stadiometer, scale and tape

**6****Description**

Blood Pressure

### Timepoint

Before intervention and 8 weeks after intervention

### Method of measurement

Mercury sphygmomanometer

## Secondary outcomes

### 1

#### Description

Adiponectin

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

Elisa kits

### 2

#### Description

Resistin

#### Timepoint

Before intervention and 8 weeks after intervention

#### Method of measurement

Elisa kits

## Intervention groups

### 1

#### Description

Intervention group : Grape Seed Extract capsules 100 mg once daily for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

daily supplementation with placebo capsules for 8 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sheykholrais Clinic

##### Full name of responsible person

Dr.Mohammad Alizadeh

##### Street address

Sheykholrais Clinic , Golbad Street

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Nutrition Research Center,Tabriz University of Medical

#### Full name of responsible person

Dr. AliReza Ostad Rahimi

#### Street address

Faculty of Nutrition, Attar Street ,Golbad Street ,Tabriz

#### City

Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Nutrition Research Center,Tabriz University of Medical

#### 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

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Faculty of Nutrition,Tabriz University of Medical Sciences,Tabriz

##### Full name of responsible person

Dr. Mohammad Alizadeh

##### Position

Ph.D. in Nutrition

##### Other areas of specialty/work

##### Street address

Daneshgah Street,Tabriz University of Medical Sciences Tabriz

##### City

Tabriz

##### Postal code

##### Phone

+98 41

##### Fax

##### Email

mdalizadeh@tbzmed.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

## **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*