

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Aug 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