

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Sep 2026

### Effect of grape seed extract on serum paraoxonase activity in different Paraoxonase Phenotypes

#### Protocol summary

##### Summary

This study is designed to determine the effect of grape seed extract on HDL-C, apolipoprotein a, apolipoprotein b, and paraoxonase and arylesterase activity in hyperlipimic patients. 70 hyperlipimic patients will be randomly allocated into case and control groups. Each group will be treated with grape seed extract as case or starch as control group at a dose of 200 mg for 2 months. All the abovementioned parameters will be measured before intervention and after 8 week intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902073812N2**  
Registration date: **2010-12-04, 1389/09/13**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-12-04, 1389/09/13

##### Registrant information

###### Name

Amir Ghorbanihaghjo

###### Name of organization / entity

Biotechnology Research Center, Tabriz University of Medical Sciences, Tabriz 51664, Iran.

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1336 3234

###### Email address

ghorbani@tbzmed.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Drug Applied Research Center

##### Expected recruitment start date

2010-04-09, 1389/01/20

##### Expected recruitment end date

2011-01-20, 1389/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of grape seed extract on serum paraoxonase activity in different Paraoxonase Phenotypes

##### Public title

Effect of grape seed extract on serum paraoxonase activity in different Paraoxonase Phenotypes

##### Purpose

Basic science

##### Inclusion/Exclusion criteria

Inclusion criteria: healthy adults with TG> 150 mg / dl and T.chol> 200mg/dl and had to be willing to cooperate. Exclusion Criteria: 1. Severe hyperlipidemia 2.Treatment by Hyperlipidemic drugs or other drugs (two months before) 3. Consumption of vegetarian diets 4. Alcoholism 5. Kidney or heart failure 6. Malignant disease 7. BMI> 30 kg/m2 8. Chronic liver disease (transaminase two times more than normal) 9. Diabetes 10. Smoking and Tobacco

##### Age

From **18 years** old to **60 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

No information

#### Sample size

Target sample size: 70

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Tabriz University of Medical Sciences

###### Street address

Tabriz University of Medical Sciences

###### City

Tabriz

###### Postal code

##### Approval date

2010-08-08, 1389/05/17

##### Ethics committee reference number

5/4/3606

### Health conditions studied

#### 1

##### Description of health condition studied

hyperlipidemia

##### ICD-10 code

E78.5

##### ICD-10 code description

Hyperlipidaemia, unspecified

### Primary outcomes

#### 1

##### Description

lipid profile changes in hyperlipidemic patients

##### Timepoint

Before and 8 week after intervention

##### Method of measurement

Spectrophotometric method

### Secondary outcomes

#### 1

##### Description

Changes in the PON activity

##### Timepoint

Before and 8 week after intervention

##### Method of measurement

Spectrophotometric method

### Intervention groups

#### 1

##### Description

Administration of grape seed extract in cases group and estimated paraoxonase activity before and 8 weeks after intervention

##### Category

Treatment - Drugs

#### 2

##### Description

Administration of placebo in control group and estimated of paraoxonase activity before and 8 weeks after intervention

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Drug Applied Research Center

###### Full name of responsible person

Dr Hasan Argani

###### Street address

Tabriz University of Medical Sciences

###### City

Tabriz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tabriz University of Medical Science-Drug Applied Research Center

###### Full name of responsible person

Dr Hossein Babaei

###### Street address

Tabriz University of Medical Sciences-Drug Applied Research Center

###### City

Tabriz

##### Grant name

##### Grant code / Reference number

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

Yes

**Title of funding source**

Tabriz University of Medical Science-Drug Applied  
Research Center

**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**

Tabriz University of Medical Science-Drug Applied  
Research Center

**Full name of responsible person**

Dr Amir Ghorbanihaghjo

**Position**

Academic Member

**Other areas of specialty/work****Street address**

Tabriz University of Medical Science-Drug Applied  
Research Center

**City**

Tabriz

**Postal code**

00984113363234

**Phone**

+98 914 314 7238

**Fax****Email**

ghorbaniamir@hotmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Science

**Full name of responsible person**

Dr Amir Ghorbanihaghjo

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Tabriz University of Medical Sciences,Tabriz,Iran

**City**

Tabriz

**Postal code**

51664

**Phone**

+98 41 1336 3234

**Fax****Email**

ghorbaniamir@hotmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Amir Ghorbanihaghjo

**Position**

PHD

**Other areas of specialty/work****Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

51664

**Phone**

+98 41 1336 3234

**Fax****Email****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*