

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Effect of grape seed extract (*Vitis Vinifera*) on lipid profile and blood pressure

#### Protocol summary

##### Summary

The aim of this randomized, double-blind clinical trial is evaluation of the effect of grape seed extract supplement on lipid profile and blood pressure in patients with borderline hyperlipidemia. In this study, 84 patients with hyperlipidemia, who are eligible, are randomly assigned in the intervention or control group. In the intervention group, the patients will receive 200 mg capsules containing grape seed extract and in the control group, the patients receive placebo with the same dose. Blood lipid profile; oxidized LDL, and blood pressure will be measured and compared in two groups after 6 weeks.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107106993N1**  
Registration date: **2011-10-14, 1390/07/22**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-10-14, 1390/07/22

##### Registrant information

##### Name

Fatemeh Mohammadi Pour

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 1322 1546

##### Email address

mohammadipor.f@lums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Razi Herbal Medicines Research Center, Lorestan  
University of Medical Sciences

##### Expected recruitment start date

2011-10-23, 1390/08/01

##### Expected recruitment end date

2011-12-22, 1390/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of grape seed extract (*Vitis Vinifera*) on lipid profile and blood pressure

##### Public title

Effect of grape seed extract (*Vitis Vinifera*) on lipid profile and blood pressure of patients with borderline hyperlipidemia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 30-60 years of age, signing informed consent for participation in the study, No known liver disease, renal failure, diabetes mellitus, no pregnancies, not using drugs affecting lipids and blood pressure, first visit to control hyperlipidemia Exclusion criteria: Having certain medical conditions that require changes in diet and exercise program, Use of other herbal medicine proven effective in reducing blood lipid and blood pressure, Failure to follow instructions and go to the doctor

##### Age

From **30 years** old to **60 years** old

##### Gender

Both

measurement of LDL,HDL,oxidized LDL,HDL,trig

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **84**

## 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

Lorestan University of Medical Sciences Research  
 Ethics Committee

##### Street address

Lorestan University of Medical Sciences, Kamalvand

##### City

khorrām Abad

##### Postal code

#### Approval date

2011-06-29, 1390/04/08

#### Ethics committee reference number

49017/200

## 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

blood lipid profile

#### Timepoint

before and after the end of study

#### Method of measurement

## Secondary outcomes

### 1

#### Description

hypertension

#### Timepoint

before and 6 week after study

#### Method of measurement

measurement of Blood pressure after 15 minutes rest.

## Intervention groups

### 1

#### Description

Capsules containing 200 mg of grape seed extract for 6 weeks

#### Category

Treatment - Drugs

### 2

#### Description

placebo with the same dose for 6 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohadaye Ashayer Clinic

##### Full name of responsible person

Dr Reza Lotfi

##### Street address

##### City

Khorrām Abad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Razi Herbal Medicines Research Center

##### Full name of responsible person

Dr Bahram Rasoulīan

##### Street address

End Raazi St

##### City

Khorrām Abad

#### Grant name

#### Grant code / Reference number

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

Yes

**Title of funding source**

Razi Herbal Medicines 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**

School of Nursing and Midwifery, Khorram Abad,  
Lorestan

**Full name of responsible person**

Fatemeh Mohammadipour

**Position**

Faculty Member

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

Department of Medical- Surgical, School of Nursing  
and Midwifery

**City**

Khorram Abad

**Postal code****Phone**

+98 66 1620 0140

**Fax****Email**

mohammadipor.f@lums.ac.ir  
f\_mohammadipoor@yahoo.com

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

Lorestan University of Medical Sciences

**Full name of responsible person**

Fatemeh Mohammadipour

**Position**

MA

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

Department of Medical -Surgical, School of Nursing  
and Midwifery

**City**

Khorram Abad

**Postal code****Phone**

+98 66 1620 0140

**Fax****Email**

mohammadipor.f@lums.ac.ir ,  
f\_mohammadipor@yahoo.com

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

Fatemeh Mohammadipour

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

+98 66 1620 0140

**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*