

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

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##### 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                                                                                                    | meassurement of LDL,HDL,oxidized LDL,HDL,trig                                       |
| <b>Phase</b><br>N/A                                                                                     | <b>Secondary outcomes</b>                                                           |
| <b>Groups that have been masked</b><br>No information                                                   | <u>1</u>                                                                            |
| <b>Sample size</b><br>Target sample size: 84                                                            | <b>Description</b><br>hypertension                                                  |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                             | <b>Timepoint</b><br>before and 6 week after study                                   |
| <b>Randomization description</b>                                                                        | <b>Method of measurement</b><br>measurment of Blood pressure after 15 minutes rest. |
| <b>Blinding (investigator's opinion)</b><br>Double blinded                                              | <b>Intervention groups</b>                                                          |
| <b>Blinding description</b>                                                                             | <u>1</u>                                                                            |
| <b>Placebo</b><br>Used                                                                                  | <b>Description</b><br>Capsules containing 200 mg of grape seed extract for 6 weeks  |
| <b>Assignment</b><br>Parallel                                                                           | <b>Category</b><br>Treatment - Drugs                                                |
| <b>Other design features</b>                                                                            | <u>2</u>                                                                            |
| <b>Secondary Ids</b><br>empty                                                                           | <b>Description</b><br>placebo with the same dose for 6 weeks                        |
| <b>Ethics committees</b>                                                                                | <b>Category</b><br>Placebo                                                          |
| <u>1</u>                                                                                                | <b>Recruitment centers</b>                                                          |
| <b>Ethics committee</b>                                                                                 | <u>1</u>                                                                            |
| <b>Name of ethics committee</b><br>Lorestan University of Medical Sciences Research<br>Ethics Committee | <b>Recruitment center</b>                                                           |
| <b>Street address</b><br>Lorestan University of Medical Sciences, Kamalvand                             | <b>Name of recruitment center</b><br>Shohadaye Ashayer Clinic                       |
| <b>City</b><br>khorram Abad                                                                             | <b>Full name of responsible person</b><br>Dr Reza Lotfi                             |
| <b>Postal code</b>                                                                                      | <b>Street address</b>                                                               |
| <b>Approval date</b><br>2011-06-29, 1390/04/08                                                          | <b>City</b><br>Khorram Abad                                                         |
| <b>Ethics committee reference number</b><br>49017/200                                                   | <b>Sponsors / Funding sources</b>                                                   |
| <b>Health conditions studied</b>                                                                        | <u>1</u>                                                                            |
| <u>1</u>                                                                                                | <b>Sponsor</b>                                                                      |
| <b>Description of health condition studied</b><br>hyperlipidemia                                        | <b>Name of organization / entity</b><br>Razi Herbal Medicines Research Center       |
| <b>ICD-10 code</b><br>E78.5                                                                             | <b>Full name of responsible person</b><br>Dr Bahram Rasouliau                       |
| <b>ICD-10 code description</b><br>Hyperlipidaemia, unspecified                                          | <b>Street address</b><br>End Raazi St                                               |
| <b>Primary outcomes</b>                                                                                 | <b>City</b><br>Khorram Abad                                                         |
| <u>1</u>                                                                                                | <b>Grant name</b>                                                                   |
| <b>Description</b><br>blood lipid profile                                                               | <b>Grant code / Reference number</b>                                                |
| <b>Timepoint</b><br>before and after the end of study                                                   | <b>Is the source of funding the same sponsor organization/entity?</b><br>Yes        |
| <b>Method of measurement</b>                                                                            |                                                                                     |

**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

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**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*