

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The cholesterol-lowering effect of Descurainia sophia

Protocol summary

Summary

Aims: The aim of this study is to compare the effect of Descurainia Sophia use alongside levostatin on LDL cholesterol reduction for the first time. **Design:** In this double - blind clinical trial, the effect of Descurainia Sophia with levostatin compared with the effect of levostatin on LDL cholesterol reduction will be studied in cardiovascular patients. **Setting and conduct:** 80 cardiovascular patients referring to the heart clinic of Shohada Ashayer hospital of Khorramabad city with high serum cholesterol level, whose disease will be approved by cardiologist. Then the patients will be divided into two groups of intervention and control. All the patients will sign the informed consent form and their serum cholesterol will be measured before and 5 months after intervention. **Participants including major eligibility:** The participants are cardiovascular patients with high cholesterol, who will randomly be divided into two groups by stratified sampling method. **Inclusion criteria:** high cholesterol level; aged between 40-70 years. **Exclusion criteria:** Patients using anti- lipids or steroids and stain; patients with diabetes and nephritic syndrome. **Intervention:** The patients will be divided into two groups randomly. Intervention group will receive 20mg of levostatin with dinner and 8 grams of Descurainia Sophia per day before lunch. The control group will receive 20mg of levostatin with dinner and placebo every day before lunch. The interventional time is 5 months for both groups. **Main outcome measures:** change in LDL cholesterol

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012612277N1**

Registration date: **2014-01-27, 1392/11/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-27, 1392/11/07

Registrant information

Name

Mahnaz Mardani

Name of organization / entity

Lorestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The cholesterol-lowering effect of Descurainia sophia

Public title

Comparing the effect of levostatin + Descurainia sophia and levostatin in lowering LDL cholesterol in patients with cardiovascular disease, A Clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: cardiovascular patients; aged between 40 to 70 years; LDL cholesterol more than 160 miligram/dl Exclusion criteria: taking anti - lipids, steroids or statins; suffering from diabetes, hypothyroids and nephritic syndrome

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will randomly be divided into two groups, by stratified sampling method. The study will be double blind. Patients and bioinformatics coworker do not know about type of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

3rd kilometer of Khorramabad- Boroujerd Road, Pardiss Complex of Education

City

Khorramabad

Postal code

6814993165

Approval date

2012-12-22, 1391/10/02

Ethics committee reference number

79123/200

Health conditions studied

1

Description of health condition studied

Cardiovascular diseases

ICD-10 code

170

ICD-10 code description

Atherosclerosis

2

Description of health condition studied

cardiovascular diseases

ICD-10 code

E78.0

ICD-10 code description

Pure hypercholesterolaemia

Primary outcomes

1

Description

Change in LDL cholesterol

Timepoint

Before intervention and 5 months after intervention

Method of measurement

With Liberman- Buchard method

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: Intervention group will take levostatin+ Descurainia sophia, that patients will take 20mg levostatin with diner+8 grams of Descurainia Sophia in 8 capsule per day with lunch for 5 months.

Category

Treatment - Drugs

2

Description

Control group:Control group will take levostatin+ placebo, that patients will take 20mg levostatin with diner+ 8 empty capsule as placebo per day with lunch for 5 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Herbal Medicine Research Center

Full name of responsible person

Dr Mahnaz Mardani

Street address

Razi Street

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Web page address
http://www.lums.ac.ir;

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Lorestan University of Medical Sciences

Full name of responsible person
Dr Mohamad Hasan Kayedi

Street address
3rd kilometer of Khorramabad-Boroujerd Road, Pardis complex of education

City
Khorramabad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Lorestan University of Medical Sciences

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
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Full name of responsible person
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Position
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Other areas of specialty/work

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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