

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of allium hirtifolium on serum lipid profile in adult patients with hyperlipidemia

Protocol summary

Study aim

Evaluation of the effect of Allium hirtifolium on serum levels of lipids

Design

Two arm parallel group, randomized, double-blind, controlled clinical trial

Settings and conduct

The study will be done in Isfahan cardiovascular research center. The selected patients will be randomly assigned to drug and placebo groups. Appropriate dietary regimen and maintaining physical activity will be recommended to two groups. Before the intervention, blood samples will be obtained from the patients of both groups and serum levels of lipids will be determined. At the end of intervention, these parameters will be measured again and recorded. Finally, the results of the two groups will be compared. The prescribing physician, laboratory staff, and data analyst will be blind to the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of more than 18 years; serum level of LDL between 100 to 160 mg/dL; having less than 2 cardiovascular risk factors Exclusion criteria: Cardiac stable angina; diabetes mellitus; diseases affecting serum level of lipids; use of drugs affecting serum level of lipids

Intervention groups

Drug group: 500-mg oral capsules of Allium, twice daily, for 6 weeks Placebo group: 500-mg oral capsules of placebo, twice daily, for 6 weeks

Main outcome variables

Serum levels of total cholesterol, TG, HDL, LDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N7**

Registration date: **2020-01-03, 1398/10/13**

Registration timing: **retrospective**

Last update: **2020-01-03, 1398/10/13**

Update count: **0**

Registration date

2020-01-03, 1398/10/13

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of allium hirtifolium on serum lipid profile in adult patients with hyperlipidemia

Public title

Evaluation the effect of allium hirtifolium in the treatment of hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of more than 18 years Serum level of LDL between 100 to 160 mg/dL Having less than 2 cardiovascular risk factors

Exclusion criteria:

Cardiac stable angina Diabetes mellitus Diseases affecting level of serum lipids Use of drugs affecting level of serum lipids

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization: Blocks of 4 will be used and patients will be assigned to drug and placebo groups based on the determined sequences in the blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo capsules will be fully similar and packaged in similar containers. The patient, the prescriber (physician), data analyst, and the laboratory personnel will be blind to the content of containers and intervention type.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar-Jerib Avenue, Vice-chancellery for research, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-07-31, 1398/05/09

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.291

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

Primary outcomes

1

Description

Serum level of total cholesterol

Timepoint

Before the intervention and the end of intervention (6 weeks after the start of intervention)

Method of measurement

Blood test

2

Description

Serum level of triglycerides

Timepoint

Before the intervention and the end of intervention (6 weeks after the start of intervention)

Method of measurement

Blood test

3

Description

Serum level of LDL

Timepoint

Before the intervention and the end of intervention (6 weeks after the start of intervention)

Method of measurement

Blood test

4

Description

Serum level of HDL

Timepoint

Before the intervention and the end of intervention (6 weeks after the start of intervention)

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Drug group: 500-mg oral capsules of Allium, twice daily, for 6 weeks

Category

Treatment - Drugs

2

Description

Placebo group: 500-mg oral capsules of placebo, twice daily, for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular Research Institute

Full name of responsible person

Rasool Soltani

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Third Moshtagh

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Web page address

<https://icri.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Research

Street address

Hezar-Jerib Ave.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patients data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available