Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of Prosopis farcta root extract capsules on lipid profile, inflammatory markers, and vascular function in patients with mild to moderate hyperlipidemia

Protocol summary

Study aim
To evaluate the effect of 8 weeks daily Prosopis farcta root extract capsule (400 mg) on LDL-C and inflammatory-vascular markers in mild to moderate hyperlipidemia

Design
Randomized, double-blind, placebo-controlled, parallel-group, phase 3 clinical trial

Settings and conduct
80 patients will be allocated in a 1:1 balanced randomised block design. Complete blinding by an independent pharmacist. Conducted in the internal medicine ward of Imam Khomeini Hospital, Ilam University of Medical Sciences

Participants/Inclusion and exclusion criteria
Eighty 18–65-year-old patients with mild-moderate hyperlipidemia (LDL-C 130–190 mg/dL or TG 150–499 mg/dL), not taking lipid-lowering drugs in the past 4 weeks. Inclusion: informed consent, BMI 18.5–35. Exclusion: pregnancy, uncontrolled diabetes, severe liver/kidney disease, advanced heart failure, Fabaceae allergy, recent statin or herbal supplement use

Intervention groups
Intervention: 400 mg standardized aqueous root extract of Prosopis farcta, one capsule daily with dinner for 8 weeks Control: identical placebo capsule, one daily for 8 weeks

Main outcome variables
Primary: change in LDL-C from baseline to week 8 Secondary: changes in TC, TG, HDL-C, hs-CRP, blood pressure, brachial FMD, quality of life (MYMOP2, SF-36), and safety

General information

Reason for update
Incorrect insertion of the scientific and common name related to the trial

Acronym
Prosopis-LIPID1404

IRCT registration information
IRCT registration number: **IRCT20230808059089N4**
Registration date: **2025-11-19, 1404/08/28**
Registration timing: **prospective**

Last update: **2025-11-25, 1404/09/04**
Update count: **1**

Registration date
2025-11-19, 1404/08/28

Registrant information

Name
MohammadHossein Sahami Gilan

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of Prosopis farcta root extract capsules on lipid profile, inflammatory markers, and vascular function in patients with mild to moderate hyperlipidemia

Public title
Studying the effect of consuming Prosopis farcta capsules on reducing blood lipids and vascular inflammation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18–65 years Mild to moderate hyperlipidemia (LDL-C ≥ 130 mg/dL and < 190 mg/dL or TG ≥ 150 mg/dL and < 500 mg/dL) according to NCEP ATP III No lipid-lowering drugs in the past 4 weeks Ability to read, write, and sign informed consent BMI 18.5–35 kg/m²

Exclusion criteria:
Pregnancy or lactation Uncontrolled diabetes (HbA1c > 8%) Severe liver (ALT/AST > 3× ULN) or kidney disease (eGFR < 30 mL/min) Heart failure NYHA class III–IV Concomitant use of strong CYP3A4 inhibitors/inducers Known allergy to Fabaceae family plants Use of herbal supplements or antioxidants in the past 2 weeks Active malignancy Systemic corticosteroid use in the past month Unwillingness to participate

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, eligible individuals will be screened based on inclusion and exclusion criteria. Then, a balanced block randomization method with block sizes of 4 and 6 will be used. Blocks used: PPGG, PGPG, PGGP, GGPP, GPGP, GPPG where P = intervention (Prosopis) and G = placebo (Placebo). The block sequence is generated by RAS (Research Analysis and Statistics) software or SealedEnvelope.com and the selection of each block is done with a random number table. Allocation is done by an independent pharmacist (outside the research team).

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention and placebo capsules are identical in shape, color, odor, taste, and packaging. Coding is performed by an independent pharmacist. Patients, the principal investigator, the data collection nurse, the laboratory assessor, and the statistical analyst are unaware of the group allocation until the final analysis. Decoding will only be performed after the database is locked and the initial statistical analysis is complete.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences

Street address
Ilam University of Medical Sciences, Ilam University of Medical Sciences, Banganjab, Ilam City, 3rd Floor, Secretariat Unit

City
Ilam

Province
Ilam

Postal code
6939177143

Approval date
2025-06-29, 1404/04/08

Ethics committee reference number
IR.MEDILAM.REC.1404.069

Health conditions studied

1

Description of health condition studied
Mild to moderate hyperlipidemia – Dyslipidemia – Disorders of lipoprotein metabolism – Early cardiovascular disease – Prevention of atherosclerosis

ICD-10 code
E78.5

ICD-10 code description
Hyperlipidemia, unspecified

Primary outcomes

1

Description
Change from baseline in mean serum low-density lipoprotein cholesterol (LDL-C) level at week 8

Timepoint
Day 0 (baseline, before starting the capsules) and Day 56 ± 3 (end of week 8 of intervention)

Method of measurement
5 mL fasting (12–14 hours) venous blood sample,

measured by enzymatic colorimetric method using Pars Azmoon commercial kit or equivalent on Hitachi 917 or Beckman Coulter AU5800 autoanalyzer, daily calibration and internal/external quality control

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Prosopis farcta root extract capsule (Syrian mesquite)Dose: 400 mg of standardized dry aqueous extract (standardized to minimum 5% total flavonoids by UV-Vis spectrophotometry)Regimen: One 400 mg capsule daily with dinner for 8 consecutive weeksDosage form: Hard gelatin capsule size 0Manufacturer: GMP-certified pharmaceutical laboratory of University Herbal Medicine Research CenterExcipients: Microcrystalline cellulose, magnesium stearate, colloidal silicon dioxideStandardized low-fat diet and moderate physical activity counseling provided at baseline

Category
Treatment - Drugs

2

Description
Control group: Placebo capsuleComposition: Lactose monohydrate + microcrystalline cellulose + magnesium stearate + trace amount of approved food coloring (to match intervention capsule exactly)Regimen: One capsule daily with dinner for 8 weeksAppearance: Completely identical to intervention capsule (size, color, smell, taste, packaging)Manufacturer: Same as intervention capsuleDiet and physical activity counseling: Identical to intervention group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Ilam

Full name of responsible person
Alireza Vasiee

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Ayatollah Heydari Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Ilam 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
Ilam University of Medical Sciences

Full name of responsible person
Alireza Vasiee

Position
Clinical Nursing Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
A decision will be made by the research team at the end of the study.
When the data will become available and for how long
A decision will be made by the research team at the end of the study.
To whom data/document is available
A decision will be made by the research team at the end of the study.
Under which criteria data/document could be used
A decision will be made by the research team at the end of the study.
From where data/document is obtainable
Contact the email address rezawest10@gmail.com.
What processes are involved for a request to access data/document
Contact the email address rezawest10@gmail.com.
Comments