

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Oct 2026

The Effect of Cydonia oblonga sauce on Obesity and Lipid Profile in Hyperlipidemic Patients Suffering From Obesity and Overweight: A Randomized Clinical Trial

Protocol summary

Study aim

Determination of the effect of quince paste consumption on obesity and lipid profile in hyperlipidemic patients with overweight and obesity

Design

Single-blind, parallel-group randomized controlled trial with block randomization

Settings and conduct

Following initial screening based on inclusion/exclusion criteria and confirmation of no indication for pharmacological therapy according to 10-year and lifetime atherosclerotic cardiovascular disease risk, informed consent is obtained. Demographic questionnaires, the International Physical Activity Questionnaire (IPAQ), and 3-day dietary recalls are completed at baseline and study end. Anthropometric measurements (height, weight, BMI, waist circumference, hip circumference, and waist-to-hip ratio) are performed. At each follow-up, a medication-related adverse effects questionnaire is completed, and health indicators are documented via clinical examination and, when indicated, paraclinical tests.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Non-menopausal women and men; hyperlipidemia (total cholesterol exceeding 200 and triglycerides exceeding 200 milligrams per deciliter); age 20–55 years; body mass index 25–39.9 Kilograms per square meter. Exclusion Criteria: Pregnancy; lactation; secondary hyperlipidemia; familial hyperlipidemia; hypertension; diabetes or prediabetes; premature family history of cardiovascular disease; triglycerides exceeding 400 milligrams per deciliter or LDL-C exceeding 190 milligrams per deciliter; indication for lipid-lowering therapy based on lipid profile and 10-year cardiovascular risk; ; allergy

Intervention groups

Control: lifestyle modification; Intervention: lifestyle

modification adjunct to quince sauce

Main outcome variables

obesity, and overweight, Blood lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260504069255N1**

Registration date: **2026-08-28, 1405/06/06**

Registration timing: **prospective**

Last update: **2026-08-28, 1405/06/06**

Update count: **0**

Registration date

2026-08-28, 1405/06/06

Registrant information

Name

soraiya mehryari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-11, 1405/06/20

Expected recruitment end date

2027-03-11, 1405/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cydonia oblonga sauce on Obesity and Lipid Profile in Hyperlipidemic Patients Suffering From Obesity and Overweight: A Randomized Clinical Trial

Public title

The Effect of Cydonia oblonga sauce on Obesity and Lipid Profile in Hyperlipidemic Patients Suffering From Obesity and Overweight: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and Non-monopausal Women Hyperlipidemia : TG>200mg/dl , TC>200 mg/dl Age range 20-55 years BMI=25 -39.9Kg/m2 Willingness to participate in the study

Exclusion criteria:

Pregnancy, breastfeeding, menopause, oophorectomy, PCOS Bone, rheumatoid, thyroid, parathyroid, cardiac, hepatic, pulmonary, renal, intestinal diseases, malignancies, and fever Familial hyperlipidemia High blood pressure Family history of premature cardiovascular disease Diabetes and Prediabetes LDL>190mg/dl, TG>400mg/d The need to initiate lipid-lowering therapy based on lipid levels and ASCVD criteria (10-year cardiovascular disease risk). Obtaining hyperlipidemia medications Presence of symptoms of an infectious, inflammatory, or surgical condition within the last three months. Use of insulin, glibenclamide, corticosteroids, or estrogen. vitamin/mineral supplementation, weight-loss drugs, or diet/exercise program within 3 months prior to or during the study. Tobacco, cigarettes, alcohol, or drugs allergy to quince or its products (e.g., sauce, jam), or quince consumption within the past 3 months."

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

They will be randomly assigned to two equal groups (30 participants per group): the control group will receive lifestyle modification, and the intervention group will receive lifestyle modification plus quince paste.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a single-blind (assessor-blinded) trial, wherein the anthropometrics and the laboratory analyst will remain unaware of the group allocation (intervention versus control).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Ethics Committee, Tabriz University of Medical Sciences, 29 Bahman Street

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5166614776

Approval date

2026-07-22, 1405/04/31

Ethics committee reference number

IR.TBZMED.REC.1405.242

Health conditions studied**1****Description of health condition studied**

High blood lipids

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

2**Description of health condition studied**

Obesity and Overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

Obesity and Overweight

Timepoint

Start of the study and end of the study (two months later)

Method of measurement

Measurement of BMI, waist circumference, and hip circumference.

Secondary outcomes

1

Description

Blood lipid profile

Timepoint

At the beginning and end of the study (two months later)

Method of measurement

Fasting venous blood samples will be obtained for the measurement of total cholesterol (TC), triglycerides (TG), and high-density lipoprotein cholesterol (HDL-C). Low-density lipoprotein cholesterol (LDL-C) levels will then be calculated using the Friedewald formula: $LDL-C = TC - HDL-C - (TG / 5)$ provided $TG < 400$ mg/dL

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Description

Cydonia oblonga sauce Side effects

Timepoint

At the beginning and end of the study (two months later)

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: 5 grams of the paste (using the provided scoop), three times daily, half an hour before meals, In addition to lifestyle measures

Category

Treatment - Other

2

Description

Control group: lifestyle measures

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Sinai Hospital

Full name of responsible person

Dr Soraiya Mehryari

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Azadi Street, between Hafez and Montazeri

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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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

Tabriz 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
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Iranian Medicine Resident
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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

No further information is available.

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