Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Initial Evaluation of Effect of Internal Septum of Juglans regia L. on Blood Lipids in Patients with Dyslipidemia: A Double-blind Placebo-controlled Randomized Clinical Trial

Protocol summary

Study aim

Initial Evaluation of Effect of Internal Septum of Juglans regia L. on Blood Lipids in Patients with Dyslipidemia: A Double-blind Placebo-controlled Randomized Clinical Trial

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 60 patients.

Settings and conduct

In this study, patients are identified and monitored in the Endocrinology Clinic of Imam Khomeini Hospital in Tehran. Patients are divided into two groups by block randomization method and receive a capsule containing internal septum of Juglans regia L. or placebo 3 times a day for 12 weeks. Patients receive their anti dyslipidemia drugs during the study. In this study, the researcher and patients are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obtain informed consent from patients. Patients aged 25 to 70 years. Patients with dyslipidemia who have serum low density lipoprotein cholesterol more than goal based on European Heart Association 2019 guideline despite receiving the maximum or maximum tolerable dose of statins. Exclusion criteria: History of walnut allergy Taking other herbal medicines Immune system defects Pregnancy Renal or liver failures Uncontrolled thyroid disease Triglyceride>350 mg/dl Drugs that increase serum glucose levels Neurological or psychiatric disorders Lactation

Intervention groups

One group of patients is given a capsule containing 500 mg of internal septum of Juglans regia L.extract and the other group is given a placebo capsule (containing 500 mg pectin) for 3 months.

Main outcome variables

Low-density lipoprotein cholesterol, Triglycerides and Lipoprotein (a)

General information

Reason for update

Due to the COVID-19 pandemic, patients do not refer to medical centers. So, it was decided to reduce the number of patients from 80 to 60. for this purpose, we consulted to a statistician.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201227049850N1**
Registration date: **2021-10-03, 1400/07/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-15, 1400/09/24**
Update count: **1**

Registration date

2021-10-03, 1400/07/11

Registrant information

Name

mehrzad mirshekari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4441 2540

Email address

mehrzad.mirshekari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Initial Evaluation of Effect of Internal Septum of Juglans regia L. on Blood Lipids in Patients with Dyslipidemia: A Double-blind Placebo-controlled Randomized Clinical Trial

Public title
Evaluation of Effect of Internal Septum of Walnut on Blood Lipids
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Obtain informed consent from patients. Patients aged 25 to 70 years. Patients with dyslipidemia who have serum LDL-C more than goal based on European Heart Association 2019 guideline despite receiving the maximum or maximum tolerable dose of statins. The therapeutic goals of LDL-C blood levels varies between 55 and 100 mg/dl based on other conditions and diseases in the study participants.
Exclusion criteria:
History of walnut allergy Taking other herbal medicines Immune system defects Pregnancy Renal failure (eGFR <30 mL / min / 1.73m2) Liver failure (AST or ALT> × 3 ULN) Uncontrolled thyroid disease (TSH <LLN or TSH> 1.5 × ULN) TG>350 mg/dl Concomitant use of any medication containing estrogen or progesterone, systemic glucocorticoids, cyclosporine, tacrolimus, everolimus, sirolimus, antipsychotic drugs, psychotropic substances or alcohol Neurological or psychiatric disorders that affect the acceptance of medication and the correct implementation of the study protocol Lactation
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization will be used to balance the number of samples assigned to each group. For this purpose, 10 blocks of 8 members with different sequences, but equal proportions are composed of two groups A and B and are numbered from 1 to 10. With the RANDBETWEEN function, 10 random number between 1 and 10 is specified, the corresponding blocks of these numbers are placed in a row, and a random chain of groups A and B is formed. Group A is selected as the intervention group and group B as the control group. In order to conceal the random allocation, 80 envelopes with aluminum wrappers (in order to obscure the contents of the envelopes) will be prepared and the letters A and B will be recorded on the cards and the cards will be placed in the envelopes in a random chain. Finally, by entering the study, patients will open the envelopes in order and their assigned group will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, both of patients and researcher are blinded. Placebo is prepared the same as the drug capsule. Drug and placebo are coded into A and B by the third supervisor and randomized by block randomization method.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
No. 4, Gharib Ave, Tehran city
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2020-12-07, 1399/09/17
Ethics committee reference number
IR.TUMS. TIPS. REC. 1399. 121

Health conditions studied

1

Description of health condition studied
Dyslipidemia
ICD-10 code
E78.5
ICD-10 code description
Hyperlipidemia, Unspecified

Primary outcomes

1

Description
Low-density lipoprotein cholesterol (LDL-C)
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Serum level measurement

Secondary outcomes

1

Description
Serum level of lipoprotein(a)
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Serum level measurement

2

Description
Serum level of triglycerides
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Serum level measurement

3

Description
Serum level of total cholesterol
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Serum level measurement

4

Description
Cholesterol ratio(low-density lipoprotein cholesterol/high-density lipoprotein cholesterol)
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Calculate Low Density lipoprotein cholesterol divided by high Density lipoprotein cholesterol

5

Description
Atherogenic index (log triglycerides/high-density lipoprotein)
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Calculate the logarithm of high-density lipoprotein cholesterol divided by triglyceride

6

Description
Weight, waist and waist to hip
Timepoint
Zero and 12 weeks after intervention
Method of measurement
Measurement with a meter

7

Description
Systolic and diastolic blood pressure
Timepoint
Zero and 12 weeks after intervention
Method of measurement
By blood pressure monitor device

Intervention groups

1

Description
Intervention group: The intervention group is treated with an oral capsule containing 500 mg of internal septum of Juglans regia L. extract three times a day for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: The control group is treated with an oral capsule containing 500 mg pectin (placebo) three times a day for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam khomeini Hospital and Shariati Hospital
Full name of responsible person
Soha Namazi
Street address
Imam Khomeini Hospital Complex, Gharib ave, Tehran city
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Tehran
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1419733141
Phone
+98 21 6119 0000
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namazisoha@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahrayan

Street address
Keshavarz Blvd, Gods Ave, Univercity Building

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Tehran

Province
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mehrzad.mirshekari@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Soha Namazi

Position
Professor of Pharmacotherapy, Tehran University of Medical Sciences

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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No. 43, Golestan Complex, Golab Ave, Sadeghiye Squere, Tehran Town

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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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