Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of Artichoke and lettuce seed combined capsule on lipid profile in patients with hyperlipidemia

Protocol summary

Study aim

Study the Effect of Artichoke and lettuce seed combined capsule on lipid profile in patients with hyperlipidemia as an effective and safe production

Design

In order to no previously clinical trial in this field, this study is considered as Pilot Study and the Sample Size in Each Group was 35 Patients by Expert Opinion. The Capsules of combined Artichoke and lettuce seed and Placebo capsules will give blinded to drugs in Patients Randomly.

Settings and conduct

Extraction and Encapsulation will be carried out at BuAli Institute and Mashhad Pharmaceutical Faculty. The Clinical Section of this Study will be conducted at Negarestan private clinic of Golbahar.In this double-blind study physician, researcher, and patients will not be Aware of how to receive capsules in the intervention and control groups until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with hyperlipidemia with criteria of cholesterol≥ 200 mg/dL; Triglyceride≥ 200 mg/dL and LDL≥100 mg / dL, Body mass index (BMI) between 19 and 30 kg/m2, Ability to Understand the Generalities of the Study and interventions and possible complications, Signing informed consent form Exclusion criteria: hypothyroidism, Menopause and pregnancy, alcohol consumption, inflammatory disease like Diabetes, cancer, chronic liver disorders (Fatty liver, Cirrhosis, Hepatitis, etc.), consumption of anti-convulsive drugs, consumption of anti-oxidant supplements

Intervention groups

Intervention group: Artichoke and lettuce seed combined Capsule Control group: Placebo Capsule

Main outcome variables

Blood lipid profile, Possible Side Effects of the Artichoke and lettuce seed combined Capsule

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130418013058N14**
Registration date: **2019-09-15, 1398/06/24**
Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name
Seyed Ahmad Mohajeri

Name of organization / entity
Pharmaceutical Research Center, School Of Pharmacy, Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 1882 3255

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mohajeria@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the effect of Artichoke and lettuce seed combined capsule on lipid profile in patients with hyperlipidemia

Public title
Effect of Artichoke and lettuce seed on lipid profile
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with hyperlipidemia with cholesterol ≥ 200 mg / dL; Triglyceride ≥ 200 mg / dL and LDL ≥ 100 mg / dL BMI between 19 and 30 kg / m 2
Exclusion criteria:
Taking antioxidant supplements Taking anti-seizure drugs Diabetes Cancer Hypothyroidism Menopause and pregnancy Smoking and alcohol Cases of chronic liver disease (Fatty liver, Cirrhosis, Hepatitis, etc.)
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
A Code will be Randomly Assigned to Each Box by the Software.The Therapist will give it to the Patient Randomly without Knowledge of the Type of Medicine. Thus, the Nature of Each Code will be Unclear Until the Analysis of the Results.
Blinding (investigator's opinion)
Double blinded
Blinding description
Artichoke and lettuce seed combined and Placebo Capsules will be Prepared with the Same Shape, Color and Weight and will be Placed in Cans with Completely the Same Uniform, Color and Shape that Coded. The Treating Physician, Researcher, and Patients will not be Aware of the Code Printed on the Container.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Mashhad university of Medical science
Street address
Deputy of Science and Technology, Mashhad University of Medical Sciences, next to the Hoveizeh cinema, Daneshgah Avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-05-19, 1397/02/29
Ethics committee reference number
IR.MUMS.REC.1397.057

Health conditions studied

1

Description of health condition studied
Hyperlipidemia
ICD-10 code
E78.0
ICD-10 code description
Pure hypercholesterolemia

Primary outcomes

1

Description
Lipid profile
Timepoint
Measurement of lipid profile at the beginning of the study (before intervention) and 6 and 12 weeks after intervention
Method of measurement
Blood test

2

Description
Probable side effects of the Artichoke and lettuce seed combined capsule
Timepoint
6 and 12 weeks after intervention
Method of measurement
reporting by patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Getting 2 combined capsule containing lettuce seed and artichoke extract per day for 12 weeks along with hyperlipidemia regimen
Category
Treatment - Drugs

2

Description
Control group: Getting 2 capsule of placebo per day for 12 weeks along with a hyperlipidemia treatment regimen
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Negarestan private clinic of Golbahar
Full name of responsible person
Amin Saeidi Nia
Street address
Bahar street
City
Golbahar
Province
Razavi Khorasan
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2

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Between shahis Javan and Shahid Al-Shahidi,Shahid Fakori Blvd., Mashhad.
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vresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Seyed Ahmad Mohajeri
Position
PhD in Pharmacology, Faculty Member of Pharmacodynamy and Toxicology, School of Pharmacy and Targete
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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A Level or less
Other areas of specialty/work
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shariarif921@mums.ac.ir

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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only some parts of data after blinding the subjects can be shared by the request of applicant
When the data will become available and for how long
After publishing article will be accessible
To whom data/document is available
Researchers and subjects in scientific and academic institutions
Under which criteria data/document could be used
After request and for scientific use as in published article can be used in scientific resources reports
From where data/document is obtainable
corresponding author
What processes are involved for a request to access data/document
Sending request to corresponding author, evaluation and if it will be confirmed, sending data and evidences to applicant
Comments