

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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  $\geq$  200 mg/dL; Triglyceride  $\geq$  200 mg/dL and LDL  $\geq$  100 mg / dL, Body mass index (BMI) between 19 and 30 kg/m<sup>2</sup>, 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)

##### Phone

+98 51 1882 3255

##### Email address

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  $\geq$  200 mg / dL; Triglyceride  $\geq$  200 mg / dL and LDL  $\geq$  100 mg / dL BMI between 19 and 30 kg / m<sup>2</sup>

### 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 committee 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

##### Postal code

0000973702

##### Phone

+98 51 3832 5716

##### Email

amin.saeidinia@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Amin Saeidinia

##### Street address

Daneshgah street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3854 3031

##### Email

emamreza@mums.ac.ir

##### Web page address

<http://emamreza.mums.ac.ir/index.php>

## 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.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177899191

##### Phone

+98 51 3841 1538

##### Email

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 Pharmacodynamics and Toxicology, School of Pharmacy and Targete

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

**Postal code**

9188617871

**Phone**

+98 51 3882 3251

**Email**

mohajerija@mums.ac.ir

## Person responsible for scientific 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 Pharmacodynamics and Toxicology, School of Pharmacy and Targete

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188617871

**Phone**

+98 51 3882 3251

**Email**

Mohajerija@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fatemeh Shahriari

**Position**

Pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188617871

**Phone**

+98 51 3882 3251

**Email**

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**