

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Investigation the effect of hydroalcoholic extract of lettuce seed on lipid profile in hyperlipidemic patients: a randomized double blind clinical trial

Protocol summary

Summary

In recent years, with socioeconomic development, changes in lifestyle, diet and the aging of the population, the incidence of hyperlipidemia has been increased. Actually, it is one of the most important public health problems which threatens human health worldwide and is associated with excessive medical expenses. Hyperlipidemia is an asymptomatic chronic condition commonly characterized by an excess of lipid profiles in the bloodstream, it can silently hurt the blood vessels, heart, brain, and kidneys. Thus, these patients have a significant and recognized risk factor for progression of atherosclerosis, cardiovascular and cerebrovascular diseases. Cholesterol is a fatty substance which is circulate in the blood and has an essential role in the body as protection for the vascular walls, linings of body organs, digestive function and a component in forming cell membranes and some hormones. But, it can also be a problem, if too much used through the diet and not metabolized or used. High level of cholesterol has been shown to destroy vascular function and structure and leading to accumulation of fatty plaques on vessel walls, narrowing veins and arteries and decreased blood flow to the heart muscle, brain, and other organs or leading to embolism. In addition, high cholesterol cause to oxidative change, which has an augmentative role in the formation of atheroma plaques in vessels wall. Generally, hyperlipidemia diagnosed by confirmed in individuals with blood cholesterol levels of >200 mg/dl or blood triglyceride levels of >180 mg/dl. Controlling hyperlipidemia also have a vital role in the prevention of hypertension, myocardial infarction, risk of stroke, coronary deaths, and overall mortality. Although, a healthy lifestyle, weight loss, and decreased dietary cholesterol have been shown to lower the risk of developing hyperlipidemia. If these interventions are not efficient, drug therapy will be necessary in decreasing hyperlipidemia. Many anticholinergic adverse effects such as weight gain or weight loss, nausea, constipation,

sedation, cardiac toxicity, orthostatic hypotension, arrhythmias, sexual dysfunction and many drug interactions may occur with antihyperlipidemic medicines. At the present years, the interest for herbal remedies as an important factor for treatment and maintenance of health is increasingly emphasized. The use of herbal remedies becomes wide spread in the world due to their low expense, availability, less side effects and drug interactions compared to the chemical drugs. *Lactuca sativa* commonly known as lettuce, is a plant species belonging to the family Asteraceae. It is most often grown as a leaf vegetable and sometimes for its stem and seeds. It is a very popular herb for salad and food. In recent pharmacological studies, lettuce has demonstrated antidiabetic, narcotic, antioxidant and anti-inflammatory activities. Phenolic acids, flavonoids, anthocyanins, and vitamins A and C are the major active compounds in lettuce. Some well-designed clinical trials have indicated the efficacy of lettuce in sleep disorder, anxiety and diabet. In this study, we investigated the hypolipidemic effect of chronic administration of aqueous ethanol extract of lettuce seed in a 12-week double-blind, placebo-controlled and randomized clinical trial. The data suggested that lettuce extract has hypolipidemic properties and should be further investigated as a potential intervention for hyperlipidemic treatment in patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011213058N5**
Registration date: **2016-10-25, 1395/08/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-25, 1395/08/04

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

Mashhad University of Medical Sciences

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of hydroalcoholic extract of lettuce seed on lipid profile in hyperlipidemic patients: a randomized double blind clinical trial

Public title

The effect of lettuce seed on hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male and female outpatients aged 25 to 65 years; incidence of hyperlipidemia with at least one of the following factors related to cholesterol > 200 mg/dl; TG> 150 mg / dl; LDL> 130 mg/dl; HDL<40 mg/dl. The exclusion criteria: the patients who had underlying diseases such as diabetes; IHD; hypertension; metabolic syndrome; peripheral vascular disease; coronary artery disease; LDL more than 190 in patients who needs medical treatment (for healthy people or with one risk factor); LDL ≥ 160 in patients they need drug treatment (for those with two or more risk factors). Risk Factors: smoking; hypertension; low HDL level (less than 40); history of coronary artery disease at an early age in the household (less than 55 years in males and in females under age 65years old).

Age

From 25 years old to 65 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 140

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Qoreishi Building, Daneshgah Street, Mashhad, Iran

City

Mashhad

Postal code

91388-13944

Approval date

2016-02-06, 1394/11/17

Ethics committee reference number

IR.MUMS.REC.1394.614

Health conditions studied

1

Description of health condition studied

hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

Cholestrol, Tg, HDL, LDL

Timepoint

Baseline, after 6th week, after 12th week

Method of measurement

Blood test

2

Description

BMI

Timepoint

Every 2 weeks

Method of measurement

Height/ weight

Secondary outcomes

1

Description

Side effects

Timepoint

Every 2 weeks

Method of measurement

Questionair

Intervention groups

1

Description

Intervention group: Prescription of lettuce seed capsules (1000mg/ day) plus atorvastatin tablet (20mg/day) in hyperlipidemic patients for 12 weeks. Participants did not receive any other hypolipidemic drugs during the trial. The patients compliance and medication side effect were estimated at each visit.

Category

Treatment - Drugs

2

Description

Control group: prescription of placebo capsules (1000mg/ day) plus Atorvastatin tablet (20mg/day) in hyperlipidemic patients for 12 week. Participants did not receive any other hypocholestrolemic drugs during the trial. The patients compliance and medication side effect were estimated at each visit.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bekran Health Center

Full name of responsible person

Maryam Hassanpour Moghadam

Street address

Shahroud road (km 80), miamey

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Ahmad Mohajeri

Street address

Faculty of Pharmacy

City

Mashhad

Grant name

Grant code / Reference number

940704

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Ahmad Mohajeri

Position

PhD, Pharm D

Other areas of specialty/work

Street address

Faculty of Pharmacy

City

Mashhad

Postal code

Phone

+98 51 3711 2611

Fax

+51 37112470

Email

mohajeria@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Ahmad Mohajeri

Position

Phd, Pharm D

Other areas of specialty/work**Street address**

Faculty of Pharmacy

City

Mashhad

Postal code**Phone**

+98 51 3711 2611

Fax

+98 51 3711 2470

Email

mohajeria@yahoo.com

Web page address

School of Pharmacy, Mashhad University of Medical Sciences, Mashhad, Iran

City

Mashhad

Postal code**Phone**

+98 51 3882 3255

Fax

+98 51 3882 3251

Email**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Pharmacy

Full name of responsible person

Maryam Hassanpour Moghadam

Position

MD.

Other areas of specialty/work**Street address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty