Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

To determine the effectiveness of Cynara Scolymus extract on lipid profile of patients with chronic kidney disease compared with placebo

Protocol summary

Summary

Objectives: According to the high prevalence of dyslipidemia and its effects on progression of chronic kidney disease and lack of research on the impact of artichokes in CKD patients, this study aimed to determine the effects of the plant on lipid profile and inflammatory factors in CKD patients. Entry criteria: The target population in this study is adult CKD patients who were referred to Imam Khomeini hospital. The study sample included all CKD patients in stage 3 (GFR: 30-59 mL/min/1.73m2), stage 4 (GFR: 15-29 mL/min/1.73m2), stage 5(GFR < 15 ml/min/1.73 m 2) with failure to control blood lipids (serum LDL ≥110 mg/dl &cholestrol ≥ 200), without exclusion criteria, also willing to participate in the study. Design,setting and conduct: This study is a randomized controlled clinical trial. Appropriate samples are selected by available sampling method. According to the statistics consult , sample size is 15 patients in each group, taking in to account the loss of samples 20 patients in each group have been administered as the sample size. For all samples, a full explanation is given about the objectives and methodology of research and samples enrolled after written informed consent. All samples have a questionnaire on demographic characteristics, clinical course that has been set is completed. Then the patient randomly divided in to two groups receiving either placebo or products of artichoke. Based on the random sequences produced by statistics consult, samples randomly divided in to two groups (capsules artichoke) and placebo (starch capsules). For the double-blind study , collection cans artichoke supplement or placebo by someone other than the researcher encoded so the lack of knowledge of each group for the researcher can be improvised by each group. The samples will be asked to fast in the next visit to clinic. At baseline in fasting , in all the participating patients, 5 ml venous blood is taken before the intervention and height and weight were also measured. Intervention: In the intervention group, the samples receive artichoke capsules (320 mg) up to six weeks, twice daily (8 am and 8 pm). In the same manner the placebo group receives placebo capsule containing starch (320 mg) and up to 2 weeks after the drugs have been followed. All samples in both intervention and control groups, routinely receive atorvastatin tablets. The samples will be asked not to change in their diet and physical activity during this study and inform researchers about any changes in their medications. Blood draw is done in the end of week 4 and 8 (after 14-12 hours of fasting) The main outcome variables: The primary outcome is the reduction of serum LDL levels. Check triglycerides, total cholesterol, HDL, ESR, CRP and serum ferritin levels and serum iron and TIBC in the plan are secondary consequences that the change in percentage of all variables compared with the baselines determined at the week 4 and 8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021622689N3**
Registration date: **2016-06-18, 1395/03/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Ebrahim Khadem Azghadi

Name of organization / entity

School of Traditional Medicine Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Tehran university of medical sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To determine the effectiveness of Cynara Scolymus extract on lipid profile of patients with chronic kidney disease compared with placebo

Public title

The effect of Cynara Scolymus on hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Entry criteria:Patients with chronic kidney disease, stage 3 (GFR: 30-59 mL/min/1.73m2); stage 4 (GFR: 15-29 mL/min/1.73m2); stage 5 (GFR< 15 ml/min/1.73 m 2); with failure to control blood lipids (serum LDL ≥110 mg/dl & cholestrol ≥ 200); without exclusion criteria; also willing to participate in the study; and at least 4 months before the start of the study have received low-fat diet and statin drugs; having a case in considered nephrology center; The willingness of patients to participate in research Exclusion criteria: History of biliary obstructive disorders and gallstones; Artichoke use at least one month before the start of the study; unwillingness to continue to cooperate or traveling or death; pregnancy and lactation; the development of side effects of drug; lack of medication over a week.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

The ethics committee of Tehran university of medical sciences

Street address

Sixth floor, , central building of the Tehran university of medical sciences , Ghods street , Keshavarz blvd

City

Tehran

Postal code

1417653761

Approval date

2016-01-02, 1394/10/12

Ethics committee reference number

IR.TUMS.REC.1394.1531

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.5 ,N18

ICD-10 code description

Kidney damage with moderately decreased GFR (30-59 mL/min) ; Kidney damage with severely decreased GFR (15-29 mL/min) ; Chronic uraemia End stage kidney disease: in allograft failure NOS on dialysis or without dialysis or transplant , Renal retinitis ,

Primary outcomes

1

Description

serum LDL concentration

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

Special kits

Secondary outcomes

1

Description

Serum triglyceride concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

Special kits

2

Description

Serum HDL concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

3

Description

Serum cholestrol concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

4

Description

Serum CRP concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

5

Description

Serum ESR concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

6

Description

Serum ferritin concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

7

Description

Serum iron concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

8

Description

Serum TIBC concentrations

Timepoint

At baseline and at the end of 4 and 8 weeks of study

Method of measurement

special kits

Intervention groups

1

Description

In the intervention group, the samples receive artichoke capsules (320 mg) up to 6 weeks twice daily (8 am and 8 pm). All samples in both intervention and control groups, routinely receive atorvastatin tablets and low salt diet. The samples will be asked not to change in their diet and physical activity during this study and inform researchers about any changes in their medications.

Category

Treatment - Drugs

2

Description

In the placebo group, the samples receive placebo capsule containing starch (320 mg) up to 6 weeks twice daily (8 am and 8 pm). All samples in both intervention and control groups, routinely receive atorvastatin tablets and low salt diet. The samples will be asked not to change in their diet and physical activity during this study and inform researchers about any changes in their medications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Special nephrology clinic of Imam Khomeini hospital

Full name of responsible person

Seyyed Mansour Getmiry doctor , specialty of internal medicine and sub-specialty of kidney disease

Street address

clinics building , Imam Khomeini hospital complex ,the end of Keshavarz blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Tehran university of medical sciences

Full name of responsible person

Masoud Yunesian

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sixth floor, central building of Tehran university of medical sciences, Ghods street, Keshavarz boulevard

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Grant name

Grant code / Reference number

94-3146-30407

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

Yes

Title of funding source

Vice chancellor for research and technology, Tehran 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

School of traditional medicine Tehran university of medical sciences ,Vice chancellor for student in

Full name of responsible person

Ebrahim Khadem

Position

Faculty member of school of traditional medicine of Tehran university , PH.D

Other areas of specialty/work

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specialty of internal medicine and sub-specialty of kidney disease,وAssociate Professor

Other areas of specialty/work

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Toktam Fakhrian

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Student of general medicine

Other areas of specialty/work

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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