Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

To determine the effectiveness of Cynara Scolymus extract on lipid profile of hemodialysis patients compared with placebo

Protocol summary

Summary

Objectives: Regarding the role of inflammatory factors, hyperlipidemia in cardiovascular diseases in hemodialysis patients and lack of research on the effect of artichoke supplement on these factors in hemodialysis patients, the present study was aimed to determine the effects of this plant on lipid and inflammatory factors in patients Hemodialysis was designed. Entry criteria:History of hyperlipidemia in hemodialysis patient; with failure to control blood lipids (serum LDL ≥100 mg/dl); with Age over 18 and under 70 years old; with dialysis 2-3 time weekly every times for 3-4 hours; with The patient's willingness to participate in the research; having a case in considered nephrology center without exclusion criteria; BMI less than 18;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.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: **IRCT2017102022689N5**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Ebrahim Khadem Azghadi

Name of organization / entity

School of Traditional Medicine Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice-Chancellor for Research (Technology & Research) Tehran University of Medical Sciences

Expected recruitment start date
2017-11-21, 1396/08/30

Expected recruitment end date
2018-02-19, 1396/11/30

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 hemodialysis patients compared with placebo

Public title
The effect of Cynara Scolymus on hyperlipidemia

Purpose
Treatment

Inclusion/Exclusion criteria
Entry criteria:History of hyperlipidemia in hemodialysis patient; with failure to control blood lipids (serum LDL ≥100 mg/dl);with Age over 18 and under 70 years old;with dialysis 2-3 time weekly every times for 3-4 hours;with The patient's willingness to participate in the research;having a case in considered nephrology center without exclusion criteria;BMI less than 18;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
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
2016-12-13, 1395/09/23

Ethics committee reference number
IR.TUMS.REC.1394.1531

Health conditions studied

1

Description of health condition studied
End stage renal disease

ICD-10 code
N17,N19

ICD-10 code description
End stage kidney disease: in allograft failure NOS on dialysis or without dialysis or transplant , Renal retinitis , Uraemic: apoplexia+ , dementia+ , neuropathy+ , paralysis+ , pericarditis

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
Dialysis section 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
Street address
sixth floor, central building of Tehran university of medical sciences, Ghods street, Keshavarz boulevard
City

tehran

Grant name

Grant code / Reference number

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

Street address

Vice chancellor for student in Tehran university of medical science , building 43 , No. 21 , Fardanesh Alley , Ghods street , Keshavarz boulevard

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Person responsible for scientific inquiries

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Tehran university of medical science ,Imam Khomeini hospital

Full name of responsible person

Seyyed mansour Gatmiri

Position

specialty of internal medicine and sub-specialty of kidney disease,۹Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran university of medical science

Full name of responsible person

hanane manghabati

Position

resident of internal medicine

Other areas of specialty/work

Street address

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City

tehran

Postal code

Phone

00

Fax

Email

hana.manghabati@gmail.com

Web page 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