Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Curcumin on serum lipid profiles and systemic inflammation in hemodialysis patients

Protocol summary

Summary

The main purpose of this study is to determine the effects of Curcumin on Lipid profile of serum and systemic inflammation in Hemodialysis patients. This study is double blinded .blinding is performed on giving supplementation and doing laboratory tests and operating data .64 Hemodialysis patients referred to the Montaserieh hospital have been enrolled. At the beginning of the study 5 ml of venous blood (for profiling of blood lipids and inflammatory markers at the beginning of the study) is taken from all patients before connecting to Hemodialysis devices and patients are divided into two groups of intervention and control by permutation block randomization. The intervention group will receive Curcumin supplementation for 8 weeks, 80 mg, 1 time per day and the control group will receive placebo (that contained starch at a rate of 0 /5 mg) once a day. All patients are asked not to change their diets and physical activities during the study and inform every kind of change in their consuming drugs to researchers. At the end of the study before connecting to Hemodialysis device, 5 ml blood is taken. Inclusion criteria: having a history of at least 6 months of Dialysis, Between the ages of 25 and 75 years old, non-catching infectious diseases particularly Hepatitis, non-consuming steroidal anti-inflammatory drugs, Nicotinic Acid, estrogen, progesterone and Curcumin supplementation at least 1 month before the beginning of the study. Exclusion criteria: high blood potassium during the study, unwillingness to continue to participate, increasing dose of anti-fat drugs, changes in patient's lifestyle or diet during the study, using herbal fat lowering medications during the study. The primary variables in this study are measuring : Triglycerides, Cholesterol, LDL, HDL and hs-crp and secondary variables are measuring: Urea, Creatinine, Albumin, Dialysis adequacy and BMI are.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022232719N1**
Registration date: **2017-05-15, 1396/02/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-15, 1396/02/25

Registrant information

Name
Maryam Hajinezhad Kabodan

Name of organization / entity
Sabzevar University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2017-04-25, 1396/02/05

Expected recruitment end date

2017-06-26, 1396/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Curcumin on serum lipid profiles and systemic inflammation in hemodialysis patients

Public title
The effect of Curcumin on serum lipid profiles and systemic inflammation in hemodialysis patients
Purpose
Prevention
Inclusion/Exclusion criteria
IInclusion criteria: The patient's tendency to participating in study and signing approval form؛ Having a history of at least 6 months of dialysis؛ age between 25-75 years old ؛ BMI between 18.5 to 30؛ Lack of infectious disease, particularly hepatitis؛ Avoiding the use of no steroidal anti-inflammatory drugs, Nicotinic Acid, estrogen, progesterone and Curcumin supplementation for at least one month before the start of the study؛ Lack of drug addiction؛ Lack of severe heart disease, liver failure and thyroid, severe gastrointestinal bleeding and peptic ulcer disease, cholelithiasis, pregnancy or lactation Exclusion criteria: Increasing of potassium in patients' blood during the study؛ unwilling to continue to participate؛Death of the patient؛ Performing kidney transplantation؛ Increasing in dose of anti-fat drugs؛ Changing patient's lifestyle or diet during the study؛ The use of herbal medicines for lipid lowering during the study؛ No adherence to study intervention of at least 9 tablets during two months of interference
Age
From **25 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
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
Ethics committee of Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences
City
Sabzevar
Postal code
Approval date
2017-02-08, 1395/11/20
Ethics committee reference number
IR.MEDSAB.REC.1395.123

Health conditions studied

1

Description of health condition studied
Hemodialyzied kidney desease patients
ICD-10 code
E18
ICD-10 code description
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description
Trigliceride، Cholestrol، LDL، HDL ، hs crp
Timepoint
Before entrances and after entrances
Method of measurement
Blood test

Secondary outcomes

1

Description
BUN، Cr، Serum Albumin ، Adequacy of Dialysis ، BMI
Timepoint
Before entrances and after entrance
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: 80 mg Sina Curcumin medicine ، once in day in during 2months .
Category
Prevention

2

Description
Control group: placebo contains 0/5 mg starch ، is given once in day during two months.
Category

Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Montaserieh
Full name of responsible person
Maryam Hajinezhad kabodan
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Sabzevar University of Medical Sciences
Full name of responsible person
Maryam Hajinezhad Kabodan
Street address
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Sabzevar
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,Sabzevar 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
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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