

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 51 3845 9101

Email address

hajinezhadm2@mums.ac.ir

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

Inclusion 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

Hemodialyzed kidney disease patients

ICD-10 code

E18

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description

Triglyceride, Cholesterol, 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

Sabzevar University of Medical Sciences

City

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

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Doctor Koushki

Position

PhD Nutrition

Other areas of specialty/work

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

Postal code

Phone

+98 51 4401 1370

Fax

Email

kooshki.nutr@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Doctor Koushki

Position

PhD Nutrition

Other areas of specialty/work

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

Postal code

Phone

+98 51 4401 1370

Fax

Email

kooshki.nutr@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mrs. doctor Koushki

Position

Philosophia Doctor Nutrition

Other areas of specialty/work

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

Postal code

Phone

+98 51 4401 1370

Fax

Email

Kooshki.nutr@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