

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of curcumin supplementation on cardiovascular risk factors and kidney function on patients with stage 3 and 4 of chronic kidney disease (CKD)

Protocol summary

Study aim

The main purpose of this study is to determine the effects of Curcumin on Lipid profile of serum and Homocysteine in patients with stages 3 and 4 of CKD.

Design

In this randomised double-blind clinical trial study, Randomization is performed through permuted blocked randomization. Sixty patients will be assigned to one of the intervention or placebo groups by using quadratic blocks and random number tables

Settings and conduct

60 patients referred to Al-Zahra hospital will be randomly divided into two groups. The intervention group will receive Curcumin supplementation for 14 weeks, 500 mg, 1 time per day and the control group will receive placebo once a day. At the beginning of the study 5 ml of venous blood (for profiling of blood lipids and Homocysteine markers) is taken from all patients. 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 5 ml blood is taken. For evaluation of dieting intake, 3 days food record will be gathered from each subject prior to the study, and at the end (after 14 weeks) of study.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Ages between 18 to 75 years old ,GFR:15-29 and GFR:30-59, no infectious diseases particularly Hepatitis, not-consuming steroidal anti-inflammatory drugs, Nicotinic Acid, estrogen, progesterone and Curcumin supplementation at least 1 month before the beginning of the study.

Intervention groups

The intervention group will receive Curcumin supplementation for 14 weeks, and the control group will receive placebo .

Main outcome variables

The primary variables in this study are measuring : Triglycerides, Cholesterol, LDL, HDL and Homocysteine and secondary variables are measuring: Urea, Creatinine, Albumin, and BMI.

General information

Reason for update

Acronym

CKD

IRCT registration information

IRCT registration number: **IRCT20130903014551N4**

Registration date: **2019-10-20, 1398/07/28**

Registration timing: **retrospective**

Last update: **2019-10-20, 1398/07/28**

Update count: **0**

Registration date

2019-10-20, 1398/07/28

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

s_m_rouhani2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2019-10-11, 1398/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin supplementation on cardiovascular risk factors and kidney function on patients with stage 3 and 4 of chronic kidney disease (CKD)

Public title

The effect of curcumin supplementation on cardiovascular factors and kidney function on patients with chronic kidney disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient's tendency to participate in study and signing approval form no use of non 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 diseases, severe gastrointestinal bleeding and peptic ulcer disease, cholelithiasis, pregnancy or lactation Age between 18-75 years old Stage 3:GFR:15-29 Stage 4:GFR:30-59

Exclusion criteria:

kidney transplantation The use of herbal medicines as lipid lowering agents Receive omega-3 fatty acids and carnitine at least 1 month before the start of the study

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through the randomization blocking method (permuted blocked randomization). Considering the sample size, each block includes 4 characters and will use AAAB combination. In the following, all possible modes from the combination will be listed and a code will be allocated to each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of blinding , the drug and the placebo are manufactured by the manufacturer in a way that is similar in appearance, shape, color and odor.Based on randomization of four-digit codes designed by Statistics Consultant and pasted on supplement and placebo packages.The researcher and the patient are not aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square, Isfahan

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2018-07-10, 1397/04/19

Ethics committee reference number

IR.MUI.Research.REC.1397.295

Health conditions studied**1****Description of health condition studied**

Chronic Kidney Disease

ICD-10 code

N25.8

ICD-10 code description

Other disorders resulting from impaired renal tubular function

Primary outcomes**1****Description**

Blood Urea Nitrogen

Timepoint

before and after intervention

Method of measurement

Biochemistry

2

Description

Serum Creatinine

Timepoint

before and after intervention

Method of measurement

Biochemistry

3

Description

Serum Albumin

Timepoint

before and after intervention

Method of measurement

Biochemistry

4

Description

Urine Creatinine

Timepoint

before and after intervention

Method of measurement

Biochemistry

5

Description

Urine Protein

Timepoint

before and after intervention

Method of measurement

Biochemistry

6

Description

parathyroid hormone

Timepoint

before and after intervention

Method of measurement

Biochemistry

7

Description

Serum Potassium

Timepoint

before and after intervention

Method of measurement

Biochemistry

8

Description

High-density lipoprotein (HDL)

Timepoint

before and after intervention

Method of measurement

blood sampling and direct measure

9

Description

Low-density lipoprotein (LDL)

Timepoint

before and after intervention

Method of measurement

blood sampling and direct measure

10

Description

Triglycerid

Timepoint

before and after intervention

Method of measurement

blood sampling and direct measure

11

Description

Hemocysteine

Timepoint

before and after intervention

Method of measurement

Biochemistry

12

Description

blood pressure

Timepoint

before and after intervention

Method of measurement

hypertension high blood pressure according to the millimeters Mercury with the use of digital indicator

Secondary outcomes

1

Description

physical activity

Timepoint

At the beginning and end of intervention

Method of measurement

physical activity record questionnaire

2

Description

dietary intake

Timepoint

At the beginning and end of intervention

Method of measurement

3-day food record

3

Description

Body mass index (BMI)

Timepoint

At the beginning and end of intervention

Method of measurement

Weight and height measurements by one person in the same center.

Intervention groups

1

Description

Intervention group: : patients in this group will receive curcumin ,500 miligram in each day, for 10 weeks.

Category

Prevention

2

Description

Control group: : patients in this group will receive One placebo capsule in each day for 10 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Mohammad Matinfar

Street address

Alzahra Hospital, Soffeh Ave.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3792 3151

Email

dr.matinfar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Morteza Safavi

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square, Isfahan

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Phone

+98 31 3792 3168

Fax

+98 31 3668 1378

Email

safavimorteza@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Morteza Safavi

Position

Proffessore

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isfahan Azadi Square, Hezar Jarib Street, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Phone

۳۶۶۸۰۰۴۸-۰۳۱.

Fax

+98 31 3668 1378

Email

safavimorteza@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Morteza Safavi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isfahan Azadi Square, Hezar Jarib Street, Isfahan
University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶.

Phone

۳۶۶۸۱۳۷۸-۰۳۱

Fax**Email**

safavimorteza@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Morteza Safavi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isfahan Azadi Square, Hezar Jarib Street, Isfahan

University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶.

Phone

۳۷۹۲۳۱۶۸

Fax

+98 31 3668 1378

Email

safavimorteza@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available