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 termuted 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)

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+98 31 3792 3183

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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 blinlding , 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
Isfehan
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 beggining and end of intervention
Method of measurement
physical activity record questionnaire

2

Description
dietary intake
Timepoint
At the beggining and end of intervention
Method of measurement
3-day food record

3

Description
Body mass index (BMI)
Timepoint
At the beggining 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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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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