Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The assessment of curcumin in comparison with placebo on the auditory neuropathy in chronic kidney disease and diabetes mellitus patients

Protocol summary

Study aim

The aim of this study is evaluation of the curcumin effect on chronic kidney (CKD) and diabetes mellitus (DM) patients.

Design

The study will be done on the CKD and DM patients. Forty eligible patients will be divided two groups (A & B) (20 patients in each group) and received curcumin and placebo respectively for 8 weeks. The level of auditory threshold, latency and intervals of I, III and V waves at the beginning and end of the study are measured and examined by the auditory brainstem response test.

Settings and conduct

The study will be performed in clinics of Shiraz University of Medical Sciences. Using the randomization method of 4 permutation blocks with a ratio of 1: 1, all possible blocks are arranged. We give these blocks a random number. Using R software, a random number is selected and sampling is performed, and finally group A and B receive curcumin and placebo respectively for 8 weeks. The characteristics of the type and dose of drugs remain constant throughout the study. Each patient will receive an order number and the medication in pre-packaged bottles. All of curcumin and placebo capsules are the same color, weight, shape and size. Patients are followed up each week by two researchers by telephone to avoid side effects. The treatment process is kept secret from clinic researchers, laboratory staff and patients.

Participants/Inclusion and exclusion criteria

The study will be done on the CKD and DM patients. Exclusion criteria are mental illness, complementary medicine methods, use of antioxidants, aspirin and warfarin, pregnancy, breast feeding and gallstone.

Intervention groups

Group A: Patients will receive one 500 mg capsule (500 mg of turmeric extract with 475 mg of curcuminoid, Karen Company) and group B: Patients will receive one placebo capsule (containing starch) daily for 8 weeks.

Main outcome variables

Auditory threshold, Glomerular filtration rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210620051629N1**
Registration date: **2021-08-18, 1400/05/27**
Registration timing: **prospective**

Last update: **2021-08-18, 1400/05/27**
Update count: **0**

Registration date

2021-08-18, 1400/05/27

Registrant information

Name

Aida Doostkam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1528

Email address

doostkam@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The assessment of curcumin in comparison with placebo on the auditory neuropathy in chronic kidney disease and diabetes mellitus patients

Public title
The assessment of curcumin in comparison with placebo on the auditory neuropathy in chronic kidney disease and diabetes mellitus patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All chronic kidney and diabetic patients with definitive diagnosis of nephrologist and endocrinologist who have been ill for more than 6 months All patients with chronic renal disease and diabetes with definitive diagnosis who have hearing impairment in the initial evaluation All chronic renal and diabetic patients with definitive diagnosis with glomerular filtration rate less than 60

Exclusion criteria:
Use of aspirin and warfarin Mental diseases Usage of other complementary medicine methods Pregnancy lactation Usage of other antioxidant drugs except Nephrovit pills Having gallstones

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of permutation bloc randomization with quadri-bloces

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the investigator and the participant are not aware of the drug. Each patient in the experimental group receives a 500 mg capsule of curcumin daily for 8 weeks, and in the control group, each patient receives starch-containing capsules for 8 weeks. Each patient receives the medication in pre-packaged bottles. All placebo drugs and tablets are the same color, weight, shape, and size.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
ZAND street, Shiraz University of Medical Sciences

City
Shiraz

Province
Fars

Postal code
71348-14336

Approval date
2021-07-11, 1400/04/20

Ethics committee reference number
IR.SUMS.REC.1400.337

Health conditions studied

1

Description of health condition studied
Chronic kidney disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Hearing threshold based on auditory brain stem responses (ABR)

Timepoint
Before intervention, After intervention

Method of measurement
Minimum hearing threshold based on auditory brain stem responses (ABR)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily consumption of one capsule of 500 mg of turmeric extract (containing 475 mg of curcuminoid, Karen Company) for 8 weeks

Category

Treatment - Drugs

2

Description
Control group: Daily consumption of one starch capsule for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nemazi hospital, Khalili hospital
Full name of responsible person
Aida Doostkam
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ZAND Ave, Shiraz University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbas Rezaeianzadeh
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Aida Doostkam
Position
MD. PhD. , Health Researcher
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Part of the data can be shared after unidentified

When the data will become available and for how long
6 months after publication

To whom data/document is available
Interested researchers in this field

Under which criteria data/document could be used
Using for research works

From where data/document is obtainable
Research and technology deputy

What processes are involved for a request to access data/document
Sending an Email to research and technology deputy.

Comments