

# 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

**Street address**

ZAND Ave, Shiraz University of Medical Sciences

**City**

Shiraz

**Province**

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**Postal code**

71348-14336

**Phone**

+98 71 3235 7282

**Email**

doostkam@sums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Abbas Rezaeianzadeh

**Street address**

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vcrdep@sums.ac.ir

**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**

Medical Pharmacy

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## Person responsible for updating data

### Contact

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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**