

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effects of curcumin supplementation on parameters of mental health, biomarkers of oxidative stress and gene expression related to insulin, lipid and inflammation in type 2 diabetic patients with cardiovascular disease

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of curcumin supplementation on parameters of mental health, biomarkers of oxidative stress and gene expression related to insulin, lipid and inflammation in type 2 diabetic patients with coronary heart disease (CHD).

##### Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive curcumin supplements (n=30) or placebo (n=30).

##### Settings and conduct

Among patients with CHD referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 45-85 years diagnosed with type 2 diabetes and coronary heart disease.  
Exclusion Criteria: Patients with thyroid disorders, Severe renal insufficiency, hepatic failure, Those experiencing an acute myocardial infarction within the past 3 months, Patients undergoing cardiac surgery within the past 3 months.

##### Intervention groups

Intervention group: 1000 mg curcumin, once a day, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally

##### Main outcome variables

Outcomes: Biomarkers of oxidative stress (primary

outcomes) and parameters of mental health, and gene expression related to insulin, lipid and inflammation (secondary outcomes) will be quantified at study baseline and end-of-trial

#### General information

##### Reason for update

The updating process was done before publishing the paper to correct the registration information.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N63**

Registration date: **2019-08-10, 1398/05/19**

Registration timing: **retrospective**

Last update: **2020-10-01, 1399/07/10**

Update count: **1**

##### Registration date

2019-08-10, 1398/05/19

##### Registrant information

###### Name

Mohammadreza Sharif

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

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+98 31 5546 3378

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-17, 1398/03/27  
**Expected recruitment end date**  
2019-07-18, 1398/04/27  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effects of curcumin supplementation on parameters of mental health, biomarkers of oxidative stress and gene expression related to insulin, lipid and inflammation in type 2 diabetic patients with cardiovascular disease

**Public title**  
The effects of curcumin supplementation in patients with coronary heart disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Inclusion Criteria: Patients aged 45-85 years People diagnosed with type 2 diabetes and coronary heart disease.

**Exclusion criteria:**

Exclusion Criteria: Patients with thyroid disorders. Severe renal insufficiency hepatic failure Those experiencing an acute myocardial infarction within the past 3 months Patients undergoing cardiac surgery within the past 3 months

**Age**  
From **45 years** old to **85 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m<sup>2</sup>) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Cardiology clinic, who is not involved in the trial and not aware of random

sequences, will be assigned the participants to the numbered bottles of capsules

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of National Institute for Medical Research Development of Iran (NIMAD)

**Street address**

National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419693111

**Approval date**

2019-06-16, 1398/03/26

**Ethics committee reference number**

IR.NIMAD.REC.1398.101

**Health conditions studied**

1

**Description of health condition studied**

Coronary Heart Disease

**ICD-10 code**

I25.9

**ICD-10 code description**

Chronic ischemic heart disease, unspecified

**Primary outcomes**

1

**Description**

Malondialdehyde

**Timepoint**

At the beginning of the study and after 12 weeks of intervention

**Method of measurement**

Spectrophotometry

**Secondary outcomes**

## **1**

### **Description**

Beck Depression Inventory

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

Questionnaire

## **2**

### **Description**

Beck Anxiety Inventory

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

Questionnaire

## **3**

### **Description**

Pittsburgh Sleep Quality Index

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

Questionnaire

## **4**

### **Description**

Expressed levels of PPAR- $\gamma$  gene

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

RT-PCR

## **5**

### **Description**

Expressed levels of LDL-R gene

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

RT-PCR

## **6**

### **Description**

Expressed levels of IL-1 gene

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

RT-PCR

## **7**

### **Description**

Expressed levels of IL-8 gene

## **Timepoint**

At the beginning of the study and after 12 weeks of intervention

## **Method of measurement**

RT-PCR

## **8**

### **Description**

Expressed levels of TGF-beta gene

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

RT-PCR

## **9**

### **Description**

Total antioxidant capacity

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

Spectrophotometry

## **10**

### **Description**

Glutathione

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

Spectrophotometry

## **11**

### **Description**

Expressed levels of VEGF gene

### **Timepoint**

At the beginning of the study and after 12 weeks of intervention

### **Method of measurement**

RT-PCR

## **Intervention groups**

### **1**

#### **Description**

Intervention group: 1000 mg curcumin, once a day, for 12 weeks orally.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally

#### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Beheshti Clinic

**Full name of responsible person**

Dr. Fariba Raygan

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

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+98 31 5554 2999

**Email**

raygan.fariba2@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

National Institute for Medical Research Development of Iran (NIMAD)

**Full name of responsible person**

Dr. Reza Malekzadeh

**Street address**

National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

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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**

National Institute for Medical Research Development of Iran (NIMAD)

**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**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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asemi\_z@kaums.ac.ir

**Web page address**

## 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