Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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
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Iran (Islamic Republic of)
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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/m2) 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-γ 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
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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
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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
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Person responsible for updating data

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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