Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effectiveness of curcumin in improving the symptoms of patients with chronic coronary syndrome: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim
Evaluating effectiveness of curcumin in improving the symptoms of patients with chronic coronary syndrome

Design
A controlled, parallel-group, triple-blind, randomized, placebo-controlled clinical trial.

Settings and conduct
This study will be a randomized, double-blind, placebo-controlled clinical trial. Patients are selected from people who refer to the special clinic of Shahid Chamran Heart Hospital in Isfahan. Adults with chronic coronary syndrome are evaluated to enter the study. For people in the drug group, curcumin soft capsules (TurmePro; produced by Gol-Daro Pharmaceutical Company) with a dose of 250 mg every 8 hours for 8 weeks, and for placebo soft capsules of placebo (produced by the same company with the same shape and packaging) with the same frequency And the duration will be prescribed. Due to the complete similarity of drug and placebo capsules and their packaging, the prescribing doctor, the person evaluating the response, the patient and the person analyzing the statistical results will be unaware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age over 18 years 2. Suffering from chronic coronary syndrome Exclusion criteria: 1. Use of products containing curcumin during the past week 2. History of acute coronary syndrome in the last 6 months 3. Having any other severe cardiac disorders

Intervention groups
Drug group: curcumin soft capsule (TurmePro; produced by Gol-Daro Pharmaceutical Company) with a dose of 250 mg every 8 hours for 8 weeks. Placebo group: Placebo soft capsule (produced by the same company with similar shape and packaging) will be prescribed with the same frequency and duration.

Main outcome variables
Changing the score of the SAQ questionnaire and checking the level of cholesterol, LDL, HDL, TG, FBS, folic acid, hs-CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150721023282N25**
Registration date: **2023-06-15, 1402/03/25**
Registration timing: **prospective**

Last update: **2023-06-15, 1402/03/25**
Update count: **0**

Registration date
2023-06-15, 1402/03/25

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-06, 1402/04/15

Expected recruitment end date
2023-10-06, 1402/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of curcumin in improving the symptoms of patients with chronic coronary syndrome: a randomized double-blind placebo-controlled clinical trial

Public title

Evaluation of the effectiveness of curcumin in improving the symptoms of patients with chronic coronary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Suffering from chronic coronary syndrome according to the guidelines of the European Society of Cardiology (ESC) published in 2019 Full consent to participate in the study

Exclusion criteria:

Using any product containing curcumin and turmeric during the last weekcontent_copyshare History of acute coronary syndrome in the last 6 months Suffering from any other heart disorders including myocarditis, cardiomyopathy and severe valvular disorder Having hyperthyroidism Having kidney failure (creatinine clearance less than 60 ml/min) Liver disorder (Child-pugh score stage B or C) Using psychoactive drugs (alcohol, marijuana, opioids, cocaine, dextroamphetamine) The use of any anti-inflammatory or antioxidant drug (corticosteroid, NSAID, vitamins C or E, coenzyme Q10 products, immunosuppressive drugs, ...) from one week before the start of the intervention Suffering from other cognitive disorders History of allergy to curcumin Difficulty hearing or speaking pregnancy breastfeeding

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method using blocks of size 4 will be used. So that all possible sequences of two drug and two placebo in each block will be made with each block being numbered. Then, using random number table, the blocks will be selected randomly and the patients will be assigned to the two groups of drug and placebo according to the the blocks sequences.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding, drug boxes containing curcumin and placebo, which are completely similar, will be coded by the manufacturing company, and the information related to the drug content of each code (drug or placebo) will be available only to that center until the end of the data analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar-Jerib Ave.

City

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Province

Isfehan

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8174673461

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.ARI.MUI.REC.1401.210

Health conditions studied

1

Description of health condition studied

Chronic coronary syndrome

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes

1

Description

Serum levels of cholesterol, LDL, HDL, TG, FBS, hs_CRP and uric acid and Changing the score of the SAQ questionnaire

Timepoint
Before and after the end of the intervention
Method of measurement
Seattle Angina Questionnaire (SAQ) and checking biomarkers of cholesterol, LDL, HDL, TG, FBS, hs_CRP and uric acid in blood samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Curcumin soft capsule (Turmepro produced by Gol Daro Pharmaceutical Company) 250 mg every 8 hours for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: placebo soft capsule (Turmepro produced by Gol Daro Pharmaceutical Company) 250 mg every 8 hours for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Special clinic of Shahid Chamran Heart Hospital, Isfahan
Full name of responsible person
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Sponsors / Funding sources

1

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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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available