

# 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

##### Name

Rasool Soltani

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7067

##### Email address

soltani@pharm.mui.ac.ir

##### 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**

Isfahan

**Province**

Isfahan

**Postal code**

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

Rasool Soltani

##### Street address

Salman Farsi street

##### City

Esfahan

##### Province

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##### Postal code

81583-88997

##### Phone

+98 31 3260 0961

##### Email

soltani@pharm.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjooy Javanmard

#### Street address

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#### City

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#### Province

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8174683461

#### Phone

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#### Email

Research@mui.ac.ir

#### 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

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Rasool Soltani

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Medical Pharmacy

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## Person responsible for scientific inquiries

#### Contact

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Esfahan University of Medical Sciences  
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Professor  
**Latest degree**  
Specialist  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Latest degree**

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Soltani@pharm.mui.ac.ir

## 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