Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of curcumin effect on preventing heart failure after myocardial infarction

Protocol summary

Study aim
Determination the efficacy of curcumin in preventing heart failure after acute myocardial infarction
Design
This is a double blind prospective placebo controlled clinical trial study which can performed in Quam hospital, Mashhad.
Settings and conduct
double blind prospective placebo controlled clinical trial study
Participants/Inclusion and exclusion criteria
patients between 18 and 80 years with STEMI who underwent successful revascularisation on culprit vessel will be included. Patients with previous MI which was lead to ejection fraction less than 50%, malignant ventricular arrhythmia, congenital heart disease, cardiogenic shock, history of suspicious or documented heart failure or decrease in left ventricular ejection fraction, patients candidate for CABG or history of previous CABG, patients with GFR less than 30, patients with autoimmune or connective tissue disorders, subjects with cancer, pregnant or breastfeeding women, psychological patients and persons who can not complete 2-month clinical followup during study, will be excluded.
Intervention groups
Group receiving curcumin and Group receiving placebo
Main outcome variables
Left ventricular ejection fraction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130829014521N19**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **registered_while_recruiting**
Last update: **2022-02-19, 1400/11/30**
Update count: **0**
Registration date
2022-02-19, 1400/11/30

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-07-23, 1400/05/01
Expected recruitment end date
2022-12-22, 1401/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of curcumin effect on preventing heart failure after myocardial infarction

Public title
Effect of curcumin on preventing heart failure
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:

ST elevation myocardial infarction Successful treatment with percutaneous coronary intervention (PCI) on related vessel to infarct

Exclusion criteria:

Previous myocardial infarction lead to ejection fraction less than 50% malignant arrhythmia congenital heart disease cardiogenic shock history of suspicious or documented heart failure or decrease in left ventricular ejection fraction patients candidate for coronary artery bypass graft (CABG) or previous CABG patients with glomerular filtration rate lesser than 30 patients with history of autoimmune or connective tissue disorders patients with cancer pregnant or breastfeeding women patients with previous documented psychological disorders patients who can not complete their 2-month clinical followups during study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated to 500mg capsule of curcumin (500mg daily) or placebo capsule, by block randomization with block size of 2. In each block, patients of each group will be exist. The order of blocks will be determined randomly in 500mg capsule of curcumin (500mg daily) and placebo capsule groups and subjects will allocated sequentially with order of admitting. Random allocation rule method was used for determination of sequences. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done by complete matching of placebo and drugs by color, size, shape and smell. Patients receive drugs (intervention or placebo groups) in closed pockets which are coded and patients are not aware of their contents. Coding will be done by one of the colleagues of the study and evaluator nurse will be blind for type of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Mashhad University of Medical Sciences

Street address

Qoreshi

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Razavi Khorasan

Postal code

9138813944

Approval date

2019-04-17, 1398/01/28

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.003

Health conditions studied

1

Description of health condition studied

ST elevation myocardial infarction

ICD-10 code

BA41.0

ICD-10 code description

BA41

Primary outcomes

1

Description

Left ventricular ejection fraction

Timepoint

baseline and 60 days later

Method of measurement

By echocardiography

Secondary outcomes

1

Description

Major adverse cardiovascular events

Timepoint

during hospitalization and 60 days after starting study

Method of measurement
documents and reports of cardiac death, recurrent MI, culprit vessels revascularisation, cardiogenic shock, severe heart failure, major arrhythmia

Intervention groups

1

Description
Intervention group: curcumin capsule 500 mg
Category
Treatment - Drugs

2

Description
Control group: placebo capsule 500mg
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
SARA KHAKI
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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
Mashhad 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
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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
No - There is not a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After finishing the study, results will be published as article.

When the data will become available and for how long
unlimited

To whom data/document is available
Researchers, Physicians, Pharmacists

Under which criteria data/document could be used
for research purposes

From where data/document is obtainable
request to corresponding author

What processes are involved for a request to access data/document
Sending request to corresponding author and explain the cause of request. If it was confirmed, it will be sent.

Comments