

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effects of Curcumin on serum level changes of lipoprotein (a) and hs-CRP as novel biomarkers in type 2 diabetic patients with coronary artery disease of less than 50% obstruction: A double-blind clinical trial study

Protocol summary

Study aim

Determination of the effect of curcumin on serum lipoprotein(a) and hs-CRP levels in diabetic type 2 patients with coronary artery disease with an obstruction angiography of less than 50%

Design

Pragmatic, community based, parallel group, double blind, randomised controlled trial

Settings and conduct

Of the patients referred to the heart department of Ghaem Hospital, 82 patients were diagnosed with mild to moderate coronary artery disease (coronary artery stenosis less than 50%) based on their angiographic findings and at the same time had type 2 diabetes. These patients were randomly divided into two groups. They were treated with sinacurcamine 80 mg / day in the form of a 80 mg capsule or placebo for 3 months, plus a routine regimen with similar standard drugs. In the laboratory of the Ghaem Hospital, 15 ml blood samples were taken from brachialis vein of patients, for examination of the biochemical tests at the beginning and three months after starting the drug treatment and then transferred to the -80 degree freezer of the medical school. The level of biomarkers was then measured.

Participants/Inclusion and exclusion criteria

Diabetic patients with type 2 diabetes mellitus, with mild to moderate coronary artery disease confirmed by angiography, candidated for standard drug treatment. People with less than 18 years of age, liver disease, pregnancy, obstructive coronary artery disease requiring revascularisation, hsCRP levels above 8, clopidogrel consumption, inflammatory and infectious diseases, immunosuppressive drugs, and acute myocardial infarction were excluded.

Intervention groups

prescription of sinacurcumin for case group and placebo in the same shape and size of curcumin capsules to

control group

Main outcome variables

Main outcome variables include: hs-CRP and LP(a) and HDL, LDL, TC and TG serum level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130811014330N4**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **retrospective**

Last update: **2018-10-30, 1397/08/08**

Update count: **0**

Registration date

2018-10-30, 1397/08/08

Registrant information

Name

Hamid Reza Rahimi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of Curcumin on serum level changes of lipoprotein (a) and hs-CRP as novel biomarkers in type 2 diabetic patients with coronary artery disease of less than 50% obstruction: A double-blind clinical trial study

Public title
The effect of Curcumin on LP(a) and hs-CRP in diabetes patients and concurrent coronary artery diseases(coronary artery disease less than 50% obstruction)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with coronary artery disease which were selected by cardiologist Male/ Female older than 18 years diabetic patients Coronary artery stenosis in angiography less than 50%
Exclusion criteria:
Pregnant and breast-feeding patients; Rheumatic disease; Chronic liver diseases; Renal diseases; Every types of malignancies; Infectious diseases in the last 3 months; Patients with any surgical procedures in the preceding 3 months; Subjects who had a history of angioplasty or coronary by-pass graft surgery; major trauma or an immunologic disease; Subjects who were using steroids, penicillin, oral contraceptive or hormone replacement therapy; Inflammatory bowel disease, psoriasis, multiple sclerosis, systemic lupus erythematosus, myasthenia gravis, autoimmune thyroiditis.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization through random number table: included patients were randomized to receive curcumin or matched-placebo for a period of 3 months. The groups were also matched regarding age. , individual, computer soft-wares

Blinding (investigator's opinion)
Double blinded

Blinding description

participants, principle investigator particularly, healthcare providers (Physicians, nurses, physiotherapists, etc.) . who care for participants during the trial, data collectors, outcome assessors. For the control group, placebo was prescribed in the shape and color and size of the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of Mashhad University of Medical Sciences

Street address

Quraish bilding of MUMS, daneshghah St, Mashhad, Iran Mashhad

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Razavi Khorasan

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13944-91388

Approval date

2016-11-17, 1395/08/27

Ethics committee reference number

IR.MUMS.fm.REC.1395.374

Health conditions studied

1

Description of health condition studied

CAD

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

Primary outcomes

1

Description

Serum level of lipoprotein (a)

Timepoint

at the baseline and 3 months after intervention

Method of measurement

ELISA

2

Description

Serum level of hs-CRP

Timepoint

at the baseline and 3 months after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

HbA1C

Timepoint

Before intervention and 3 months after intervention

Method of measurement

autoanalyzer bt3000

2

Description

fast blood sugar (FBS)

Timepoint

Before intervention and 3 months after intervention

Method of measurement

autoanalyzer bt3000

Intervention groups

1

Description

The intervention group received routine treatment of heart disease and DMII in accordance with, the administration of curcumin. 1 Soft gel ((SinaCurcumin® (as nano-micelle 80 mg per day)) will be gave to patients for three months. Also, people underwent routine treatments of B-blockers, Aspirins, diuretic drugs, Athro-statins, vasodilators such as NO for heart diseases and metformin and glibanglamide for diabetes.

Category

Treatment - Drugs

2

Description

Control group: In this group, the placebo contains inert oil, with the same color as the drug that the drug manufacturer has produced, was given to patients with heart disease and diabetes for a period of three months, in terms of shape and size, similar to the medicine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital in Mashhad

Full name of responsible person

Dr Mostafa Dastani

Street address

Ghaeem hospital, Ahmadabad Blvd, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences,vice chancellor for research

Full name of responsible person

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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,vice chancellor for research

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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Rahimi

Position

MD, Ph.D, assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

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Position

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Latest degree

Medical doctor

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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