Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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

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Name of organization / entity
Mashhad University of Medical Sciences

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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 curcmin 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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Province

Razavi Khorasan

Postal code

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 glibangelamide 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
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Sponsors / Funding sources

1

Sponsor
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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
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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