

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The survey of oral intake effect of nano micelles curcumin on lipid profile , inflammatory markers and stress oxidative factors in patients undergoing the coronary elective angioplasty; a placebo-controlled randomized clinical trial double-blind.

Protocol summary

Study aim

The determination of lipid profile including total cholesterol, triglycerides, high-density lipoprotein (HDL), and low-density lipoprotein (LDL) and inflammatory factors including Interleukin 1 beta(IL-1), high-sensitivity C-reactive protein (hs-CRP), Tumor necrosis factor alpha (TNF α) and antioxidant factors including total antioxidant capacity(TAC), superoxide dismutase enzymes, glutathione peroxidase, and malondialdehyde concentration

Design

In this study, 90 coronary eligible patients undergoing stenting that referred to a special cardiology clinic of Golestan Hospital in Ahvaz were chosen. Participants are randomly assigned to three intervention and control groups and each participant is assigned a code.

Settings and conduct

This study is a randomized double-blind clinical trial. Cardiac patients undergoing coronary angioplasty and refer to the cardiology and cardiology clinic of Ahvaz Golestan Hospital are enrolled by a specialist heart consultant for this study. Then, 90 coronary patients were selected and randomly divided into three intervention and control groups. In this study, the investigator and the patient will be blinded to drugs and placebo.

Participants/Inclusion and exclusion criteria

Men and women with coronary artery stenosis who are willing to participate in the study.

Intervention groups

First intervention group: the group receiving nanomicell curcumin (80 mg daily) Second intervention group: the group receiving Curcumin (80 mg daily) Control group: placebo group

Main outcome variables

Lipid profile, Inflammatory factors, Antioxidant indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141025019669N6**

Registration date: **2017-12-17, 1396/09/26**

Registration timing: **prospective**

Last update: **2017-12-17, 1396/09/26**

Update count: **1**

Registration date

2017-12-17, 1396/09/26

Registrant information

Name

Hossein Khadem Haghighian

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 28 3375 2135

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of oral intake effect of nano micelles curcumin on lipid profile , inflammatory markers and stress oxidative factors in patients undergoing the coronary elective angioplasty; a placebo-controlled randomized clinical trial double-blind.

Public title

Survey of effect of curcumin in coronary patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients undergoing the coronary elective angioplasty.

Exclusion criteria:

Patients with coronary problems in last month Patients with liver, gastrointestinal disorders and inflammatory diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients of both sexes are randomly divided into four groups, intervention and control groups, using randomized distribution method. In this study, the patient and researcher are blinded to medicine and placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jondishapur University Of Medical Sciences

Street address

Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2017-07-08, 1396/04/17

Ethics committee reference number

lr.ajums.rec.1396.0638

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease

Primary outcomes

1

Description

Lipid profile

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

2

Description

Inflammatory factors

Timepoint

Before the intervention and after the intervention

Method of measurement

Eliza

Secondary outcomes

1

Description

Antioxidant indices

Timepoint

Before intervention and after intervention

Method of measurement

Eliza

2

Description

Malondialdehyde concentration

Timepoint

Before intervention and after intervention

Method of measurement

Eliza

Intervention groups**1****Description**

First intervention group: nanomicell curcumin, daily 80 mg

Category

Treatment - Drugs

2**Description**

Second intervention group: Curcumin, daily 80 mg

Category

Treatment - Drugs

3**Description**

Control group: Plasebo

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Cardiology Clinic of Ahvaz Golestan Hospital

Full name of responsible person

Dr. Bizhan Helli

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Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Bizhan Helli

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data on primary and secondary outcomes will be published.

When the data will become available and for how long

After completing the study and analyzing the data

To whom data/document is available

All researchers

Under which criteria data/document could be used

There is no objection to the use of data provided the source of the resource.

From where data/document is obtainable

IRCT site

What processes are involved for a request to access data/document

Six months after the study

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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