Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 (TNFα) 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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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
Ir.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

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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
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Nutrition
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Person responsible for updating data

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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