Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The study of the effect of nano-curcumin supplementation on biomarkers of endothelial function and inflammation in overweight or obese patients with Coronary Slow Flow Phenomenon

Protocol summary

Study aim

To investigate the effect of nano-curcumin supplementation on biomarkers of endothelial function and inflammation in overweight or obese patients with Coronary Slow Flow Phenomenon

Design

Randomized, double-blind, placebo-controlled, parallel trial with two arms (each arm includes 21 patients and overall sample size is 42) and stratified permuted block randomization is used.

Settings and conduct

Patient selection from Rajaie Heart Hospital, Tehran Taking one capsule per day for 12 weeks Blood sample collection, bio-electrical impedance analysis of body composition, and filling out questionnaires before and after the intervention Blinding patients and investigators by using identical boxes with either code A or B for nano-curcumin or placebo without knowing the content of each box

Participants/Inclusion and exclusion criteria

Inclusion criteria: 35 to 70 years old men and women with body mass index between 25 to 39.9, angiographically diagnosed as coronary slow flow phenomenon, with coronary stenosis less than 40% and left ventricular ejection fraction higher than 45%, by giving informed consent Exclusion criteria: Premature menopause, addiction and alcohol consumption, regular exerciser, routine use of anticonvulsants, corticosteroids, immunosuppressants, antiinflammatory and aphrodisiac medication or antioxidants, omega3, vitamin B12, folic acid or vitamin B6 supplements, uncontrolled hypertension, past medical history of thyroid, renal, hepatic, hematologic, autoimmune, systemic, connective tissue, pulmonary and heart diseases, malignancy

Intervention groups

1.The group taking nano-curcumin 80 mg soft gel capsules 2. The group taking placebo soft gel capsules (Both provided by Exir Nano Sina Co.)

Main outcome variables

Serum levels of adropin,endocan,homocysteine,visfatin,hs-CRP,uric acid,Different aspects of angina and quality of life evaluated by Seattle Angina and SF-36 Questionnaire

General information

Reason for update

As Coronary Slow Flow Phenomenon is an uncommon disease and on the other hand we had limited inclusion criteria , we had to widen some of inclusion criteria. For example, we extended age range to 35-70 years old , body mass index to 25-39.9 and ejection fraction ≥45%. More over we omitted smoking as an exclusion criterium. Stratified Permuted Block Randomization is used for randomization. Being smoker was added to confounding factors and smokers got point 1 and non-smokers got point 0 . Considering the previous confounding factors , sum of all points will be a score between 0-6. The patients with scores 3 and below will be considered as low risk and patients with scores equivalent to or higher than 4 will be considered as high risk for condition of the disease and then, they will go through stratified randomization according to their risk level. Since in a concurrent approved project we studied the effects of nano curcumin on some inflammatory factors on this population , the purpose of this study is changed to “the study of the effect of nano-curcumin supplementation on biomarkers of endothelial function and inflammation in overweight or obese patients with Coronary Slow Flow Phenomenon”. For this reason , serum visfatin , hs-CRP , uric acid and 36-items short form quality of life questionnaire were added as primary outcomes. Also Blood Urea Nitrogen , creatinine , Fasting Blood Sugar , insulin , Hemoglobin A1C and CBC were measured to secondary outcomes.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131125015536N8**
Registration date: **2019-06-19, 1398/03/29**
Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**
Update count: **1**

Registration date

2019-06-19, 1398/03/29

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 3059

Email address

mhosseinzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2020-04-02, 1399/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the effect of nano-curcumin supplementation on biomarkers of endothelial function and inflammation in overweight or obese patients with Coronary Slow Flow Phenomenon

Public title

Effect of Nano-curcumin in Coronary Slow Flow Phenomenon

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

35 to 70 years old men and women BMI range: 25 - 39.9 Angiographically diagnosed as coronary slow flow phenomenon by Corrected TIMI Frame Count (CTFC) method which is equivalent to 27 or higher for one or more coronary vessels. Normal coronary vessels with coronary stenosis less than 40% Left ventricular ejection fraction higher than 45% Giving informed consent for participation in the study

Exclusion criteria:

Premature menopause addiction or alcohol consumption Routine use of NSAIDs or antioxidants one month prior to study Use of aphrodisiac medication within 9 months before study Routine use of corticosteroids or immunosuppressants Use of anticonvulsants Taking antioxidant or omega3 supplements (more than 3 grams per day) at least twice a week within 3 months prior to study Taking vitamin B12, folic acid or vitamin B6 supplements within one month before study Being a professional athlete or execising regularly Uncontrolled hypertension defined as diastolic blood pressure above 90 mmHg, systolic blood pressure above 140 mmHg. Past medical history: hypothyroidism or hyperthyroidism Malignancy Chronic obstructive pulmonary diseases Systemic diseases Connective tissue diseases Renal failure Liver failure Autoimmune diseases Myocardial Infarction Sever heart failure Heart transplant Revascularization procedure or PCI or CABG Left ventricular dysfunction or echocardiographically diagnosed left ventricular hypertrophy Cardiac conduction disturbances Valvular heart disease Atrial fibrillation Aneurysms Cardiomyopathy Congenital heart disease Coronary artery disease Hematologic disorders

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Study participants will be assigned to nano-curcumin or placebo groups by stratified permuted block randomization. As the first step, we will have stratified randomization for gender. Then, either points 1 or 0 will be given to various confounding factors in this study. For example, having family history of coronary artery disease: 1 and no family history of CAD: 0, diabetes mellitus:1 , no diabetes mellitus: 0 hypertention: 1, no hypertention: 0 dyslipidemia: 1 , no dyslipidemia: 0 smoker:1 , non-smoker:0 Using any of these medications: ACE-I, ARBs, beta-blockers, statins, anticoagulants, calcium channel blockers and nitrates: 0, no use: 1. The sum of these points will be a score between 0 to 6 for each patient. The patients with scores 3 and below will be considered as low risk and patients with scores equivalent to or higher than 4 will be considered as high risk for condition of the disease and then, they will go through stratified randomization according to their risk level. Patients are randomized by using permuted blocks of size 4 and 6 (specific random number tables will be used).

Blinding (investigator's opinion)

Double blinded

Blinding description

Using identical boxes with either A or B code labels for nano-curcumin and placebo supplements, will help to

blind both patients and investigators.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Sixth Floor, Central Organization of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd,Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-05-06, 1398/02/16
Ethics committee reference number
IR.TUMS.VCR.REC.1398.109

Health conditions studied

1

Description of health condition studied
Coronary Slow Flow Phenomenon (CSFP)
ICD-10 code
I20.8
ICD-10 code description
Other forms of angina pectoris

Primary outcomes

1

Description
Serum Homocysteine levels
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Enzymatic Kit

2

Description
Serum Adropin levels
Timepoint
Before and after 12 weeks of intervention
Method of measurement
ELISA kit

3

Description
Serum Endocan levels
Timepoint
Before and after 12 weeks of intervention
Method of measurement
ELISA kit

4

Description
Different aspects of angina pectoris
Timepoint
Before and after 12 weeks of intervention
Method of measurement
Seattle Angina Questionnore

5

Description
serum visfatin level
Timepoint
Before and after 12 weeks of intervention
Method of measurement
ELISA kit

6

Description
serum hs-CRP level
Timepoint
Before and after 12 weeks of intervention
Method of measurement
ELISA kit

7

Description
serum uric acid level
Timepoint
Before and after 12 weeks of intervention
Method of measurement
enzymatic kit

8

Description
Quality of life
Timepoint
Before and after 12 weeks of intervention
Method of measurement
SF-36 items questionnaire

Secondary outcomes

1

Description
Body composition analysis
Timepoint

Before and after 12 weeks of intervention

Method of measurement

Bio-electrical impedance analysis

2

Description

Serum lipid profile

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Enzymatic Kit

3

Description

Serum alkaline phosphatase levels

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Enzymatic Kit

4

Description

serum insulin level

Timepoint

Before and after 12 weeks of intervention

Method of measurement

ELISA kit

5

Description

serum urea level

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Enzymatic Kit

6

Description

serum creatinine level

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Enzymatic Kit

7

Description

Fasting Blood Sugar

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Enzymatic Kit

8

Description

Hemoglobin A1C

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Turbidimetry

9

Description

Complete Blood Count(CBC)

Timepoint

Before and after 12 weeks of intervention

Method of measurement

Sysmex

Intervention groups

1

Description

Intervention group: Dietary supplement nano-curcumin 80 mg one capsule daily (Exir Nano Sina Co.)

Category

Treatment - Other

2

Description

Control group: Placebo supplement one capsule daily (Exir Nano Sina Co.)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei cardiovascular, medical and research center

Full name of responsible person

Ata Firouzi

Street address

Valiasr Ave, Niayesh Intersection, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

atafirouzi@yahoo.com

Web page address

http://rhc.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Sixth floor, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mahsa Rezaei
Position
M.Sc Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No: 44, Hojjat-dost Alley, Naderi St., Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416643931
Phone
+98 21 8895 5975
Fax
+98 21 8898 4861
Email
mahsarezaei1372@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad-Javad Hosseinzadeh-Attar
Position
MD, PhD, Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No.44, Hojjatdoust Alley, Naderi Ave, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1416643931
Phone
+98 21 8895 5569
Fax
+98 21 8898 4861
Email
mhosseinzadeh@tums.ac.ir
Web page address
https://www.tums.ac.ir/faculties/mhosseinzadeh

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mitra Soltani
Position
M.Sc Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No: 44, Hojjat-dost Alley, Naderi St., Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416643931
Phone
+98 21 8895 5975
Fax
+98 21 8898 4861

Email
mitrasoltani1937@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"There is no further information"
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