Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of curcumin supplementation on non invasive arterial stiffness indices in metabolic syndrome patients

Protocol summary

Study aim
Determination of the effect of curcumin supplementation on non invasive arterial stiffness indices in metabolic syndrome patients

Design
Clinical trial with control group, parallel groups, double blind, randomized

Settings and conduct
The site of this study is Imam Reza Hospital in Mashhad. Eighty patients with metabolic syndrome will be studied. Individuals are randomly divided into two groups of curcumin and placebo. At the beginning and the end of the study, anthropometric and arterial stiffness indices are measured.The level of physical activity is obtained using a questionnaire. The 48-hour food recall and the food frequency questionnaire are completed. Also a blood sample is taken to measure lipid profile, liver enzymes and fasting blood suger. In this study, participants, original researcher and sphygmocor machine operator are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria • willingness to participate in the study and the completion of informed consent form • metabolic syndrome Patients exclusion criteria • Curcumin sensitivity • Regular use of anti-diabetes drugs, antiplatelet drugs, statins, antioxidant supplements, anti-inflammatory drugs, analgesics • Use of multivitamin or herbal supplements • Liver disease, autoimmune disease, biliary disease, obstructive disease, diabetes, kidney failure, malignancy, Gallstone, calcium oxalate stones • Pregnancy and breastfeeding • Drug abuse • Smoking hookah or cigarettes

Intervention groups
Intervention group: A single dose of curcumin (500 mg) for 12 weeks. Control group: A single dose of placebo for 12 weeks

Main outcome variables
Augmentation Index, Augmentation Index75, pulse wave velocity, Augmentation pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180619040151N2**
Registration date: **2018-12-27, 1397/10/06**
Registration timing: **prospective**

Last update: **2018-12-27, 1397/10/06**
Update count: **0**

Registration date
2018-12-27, 1397/10/06

Registrant information

Name
Abdolreza Norouzy

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3800 2382

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norouzya@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of curcumin supplementation on non invasive arterial stiffness indices in metabolic syndrome patients

Public title
The effect of curcumin on arterial stiffness
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study and the completion of informed consent form Metabolic syndrome Patients
Exclusion criteria:
Curcumin sensitivity Regular use of anti-diabetes drugs, antiplatelet drugs, antioxidant supplements, anti-inflammatory drugs, analgesics Use of multivitamin or herbal supplements at least 3 months before the start of the study Liver disease, autoimmune disease, biliary disease, obstructive disease, diabetes, kidney failure, malignancy, kidney stones, calcium oxalate stones Pregnancy and breastfeeding Drug abuse Smoking hookah or cigarettes
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, stratified randomization will be used. First, the participants will be stratified based on age and sex (male or female) and then they will be allocated to intervention or placebo group based on the blocks of size 4. Blocks of size 4 have 10 modes(AABB, ABAB, BBAA, BABA, AAAB, BBBA, AAAA, BBBB, ABBB, BAAA).
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the original researcher who is responsible for randomization, Giving supplements and drafting the article is blind. Also, participants are aware of their participation in the research project but they do not know which study group they are in. The sphygmocor apparatus operator, which is responsible for evaluating arterial stiffness indices, is also blind in this study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
99191-91778
Approval date
2018-12-10, 1397/09/19
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.452

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pulse wave velocity
Timepoint
At the beginning and the end of the study
Method of measurement
Sphygmocor xcel

2

Description
Central Augmentation Index
Timepoint
At the beginning and the end of the study
Method of measurement
Sphygmocor xcel

3

Description
Central Augmentation Index75
Timepoint
At the beginning and the end of the study
Method of measurement
Sphygmocor xcel

4

Description
Central augmentation pressure
Timepoint
At the beginning and the end of the study
Method of measurement
Sphygmocor xcel

5

Description
Brachial blood pressure
Timepoint
At the beginning and the end of the study
Method of measurement
Sphygmocor xcel

6

Description
Central blood pressure
Timepoint
At the beginning and the end of the study
Method of measurement
Sphygmocor xcel

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving a single dose of curcumin (500 mg) for 12 weeks. Patients receive their supplement every four weeks. Supplement should be eaten with food.
Category
Prevention

2

Description
Control group: Receiving a single dose of placebo for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospitl
Full name of responsible person
Saeed Eslami
Street address
Ebne Sina Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
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
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
Abdolreza Norouzy
Position

Associate professor

Latest degree
Specialist

Other areas of specialty/work
Nutrition

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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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available