

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effects of curcumin on the cardiopulmonary efficacy in subjects with central obesity: A Randomized, Double-Blind, Placebo-Controlled Trial

Protocol summary

Study aim

To determine the effects of curcumin on cardiopulmonary efficacy in subjects with central obesity

Design

This is a triple blinded randomized controlled clinical trial phase II with a parallel group design of 50 subjects, in which a random number table was used for randomization.

Settings and conduct

Subjects include individuals with central obesity who refer to Persian cohort of the Mashhad University of Medical Sciences. All volunteers, care providers and statistician are blinded after assignment to intervention. So that, the supplements containers were coded as A and B by a non-researcher person and remained confidential until data analysis. The placebos are similar to the supplements regarding the weight and color. Subjects will be randomly assigned to one of two study groups and will receive 500 mg of curcumin or placebo over 56 days. Fasting blood samples are taken from all individuals before and after the intervention. Cardiopulmonary exercise testing (CPET) will be measured for all participants by a trained expert and physician before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18-65 years old, Subjects with central obesity based on the US National Cholesterol Education Programme Adult Treatment Panel III (NCEP ATP III) guidelines; Exclusion criteria: History of systemic diseases, History of cardiac ischemia, Pregnancy, Breastfeeding, Hepatic failure, Hepatic failure, Biliary obstruction

Intervention groups

The drug group (n = 25), will receive the curcumin and the control group (n = 25), will take the placebo of the same shape, weight and color with the drug at a dose of 500 mg/day over 56 days.

Main outcome variables

maximal oxygen consumption ($\dot{V}O_{2max}$)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210413050958N6**

Registration date: **2022-07-31, 1401/05/09**

Registration timing: **prospective**

Last update: **2022-07-31, 1401/05/09**

Update count: **0**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name

Maryam Saberi-Karimian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3764 3808

Email address

saberikm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-01, 1401/08/10

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of curcumin on the cardiopulmonary efficacy in subjects with central obesity: A Randomized, Double-Blind, Placebo-Controlled Trial

Public title

Effect of curcumin on cardiopulmonary efficacy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Signed informed consent form Aged 18-65 years old
Subjects with central obesity based on NCEP-ATP III guidelines

Exclusion criteria:

History of systemic diseases History of cardiac ischemia
Pregnancy Breastfeeding Hepatic failure Biliary obstruction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

The statistician generates a random allocation sequence using the block randomization method. So that blocks with size 4 and 2 of the combination of letters A and B (ABBA, ABAB, AABB, BAAB, BBAA, BABA), (AB and BA) are selected to the required number using a table of random numbers and individuals are assigned to groups according to the created sequence. Subjects are divided into one of two intervention/control groups using a table of random numbers, so that who enrolled the trial can select a sealed envelope with random allocation sequence to the intervention or control group. An expert outside the research team blinds the drugs. The executive team register the subjects and assign them to the intervention. All volunteers, the executive team, and the statistical analyst will be blinded by the interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

The random allocation sequence is made using the table of random numbers. Sequentially numbered sealed envelopes are used to implement the random allocation sequence which opened by a person not involved in the project. The participants, care providers and statistician are blinded after assignment to intervention. So that, the powders bottles are coded by a non-researcher person and remain confidential until data analysis. Moreover, In addition, placebo powder is similar to supplement

powder in shape, weight and color.

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

Ghoreishi buildings, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.212

Health conditions studied**1****Description of health condition studied**

central obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes**1****Description**

maximal oxygen consumption ($\dot{V}O_{2max}$)

Timepoint

Before the intervention and 8 weeks after taking supplement or placebo

Method of measurement

cardiopulmonary exercise testing

Secondary outcomes**1****Description**

ratio of minute ventilation to carbon dioxide output (VE/V

CO2)
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

2

Description
Dead-space ventilation (Vd/Vt)
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

3

Description
alveolar-arterial oxygen pressure gradient [P(A-a)O₂]
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

4

Description
Blood pressure
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
sphygmomanometer

5

Description
Fasting blood sugar
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
Auto analyzer

6

Description
Lipid profile (Total cholesterol, Triglyceride, High density lipoprotein, Low density lipoprotein)
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
Auto analyzer

7

Description
Anaerobic threshold
Timepoint

Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

8

Description
Peak heart rate
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

9

Description
Heart rate reserve
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

10

Description
Peak work
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

11

Description
Ventilator reserve
Timepoint
Before the intervention and 8 weeks after taking supplement or placebo
Method of measurement
cardiopulmonary exercise testing (CPET)

12

Description
Respiratory frequency
Timepoint
cardiopulmonary exercise testing (CPET)
Method of measurement
cardiopulmonary exercise testing (CPET)

Intervention groups

1

Description
The treatment group (n= 25) including subjects with central obesity based on NCEP-ATP III. Curcumin (C3 complex) at a dose of 500 mg/day plus 5 mg piperine is taken orally over 8 weeks purchased from Sami Labs LTD

(Bangalore, India) in the intervention group.

Category

Treatment - Drugs

2**Description**

The control group includes subjects with central obesity based on NCEP-ATP III. Placebo at a dose of 500 milligram per day containing 5 mg of piperine too that purchased from Sami Labs LTD (Bangalore, India) and are the same shape and color with curcumin that is received orally by control group over 8 weeks.

Category

Placebo

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

Imam Reza hospital

Full name of responsible person

Mahmoud MohammadZadeh Shabestari

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Imam Reza Hospital, Ibn Sina Street

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

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

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Research Council, Ghoreishi bildings, Daneshgah Ave.

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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

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

Maryam Saberi-Karimian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Saberi-Karimian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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

Raw data will be shared upon a reasonable request from the corresponding author.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Yes - There is 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

Title and more details about the data/document

Following a reasonable request, deidentified data will be shared.

When the data will become available and for how long

After publication of paper(s) upon a reasonable request

To whom data/document is available

Study PI and executive team

Under which criteria data/document could be used

For reasonable research or clinical purpose

From where data/document is obtainable

Maryam Saberi-Karmian

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

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Comments