

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Study of the effect of nanomicelles curcumin on glycemic control, serum lipid profile ,blood pressure and anthropometric measurements in patients with metabolic syndrome

Protocol summary

Study aim

Determination of the effect of supplementation with nanomicelles curcumin on glycemic control, serum lipid profile, blood pressure and anthropometric indices in patients with metabolic syndrome

Design

Double-blind randomized clinical trial with parallel groups

Settings and conduct

Patients with metabolic syndrome referring to the endocrine clinic of Shohadaye yaft abad and Pars hospital, who have criteria for entering the study, will be aware of the method and goals of the study and each patient will write informed consent if they have a tendency to participate in the study. At the start and after the end of the intervention, 10 cc blood will be taken from patients after 12-14 hours fasting .At baseline Their height and weight will be measured.Then, in order to control the confounding factors , they will be randomly assigned to nanomicelles curcumin and placebo group. Patients in nanomicelles curcumin group will received a 80 mg capsule daily and patients in placebo group will received a placebo capsule daily for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Tendency for cooperation -Age between 18-70 years old -BMI between 25-40 kg/m² - Having metabolic syndrome according to NCEP ATP III criteria(if 3 or more of five criteria are met) Exclusion criteria: -Pregnancy -Lactation -Insulin therapy -Having thyroid dysfunction -Having kidney disease -Having unusual diet -Use fat burner and weight lose drug

Intervention groups

Each patient will write informed consent if they have a tendency to participate in the study. After randomization, patient in study group will receive a capsule of nanomicelles curcumin daily and patient in control group will receive placebo capsule daily for 12 weeks.

Main outcome variables

Fasting blood glucose, insulin, hemoglobin A1c, total cholesterol, LDL-C and HDL-C, triglyceride, blood pressure, HOMA-IR, HOMA-B

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150815023617N3**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 22077424

Email address

golbonsohrab@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-30, 1397/03/09

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effect of nanomicelles curcumin on glycemic control, serum lipid profile ,blood pressure and anthropometric measurements in patients with metabolic syndrome

Public title
nanomicelles curcumin in metabolic syndrome

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Tendency for participation Age between 18-70 years old BMI between 25-40 kg/m2 Having metabolic syndrome according to the NCEP ATP III definition(if patient have three or more of the following five criteria): waist circumference over 120 cm (men) or 89 cm (women), blood pressure over 130/85 mmHg, fasting triglyceride (TG) level over 150 mg/dl, fasting high-density lipoprotein (HDL) cholesterol level less than 40 mg/dl (men) or 50 mg/dl (women) and fasting blood sugar over 100 mg/dl.
Exclusion criteria:
Pregnancy Lactation Use insulin injection Thyroid disorder Renal disease Having unusual diet during 3 last month Use weight loss and fat burner drugs

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **21**

Randomization (investigator's opinion)
Randomized

Randomization description
Supplements and placebo will be identified with codes A, B, and researchers do not know how the codes will be distributed. Then, from the table of four blocks(A and B), 13 blocks will be randomly selected, and these blocks will be placed behind each other. Then, 25 envelopes will be provided and the name of the group A or B put in each envelope . These envelopes will be referred to individuals, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
Supplements and placebo will be identified with codes A, B, and researchers do not know how the codes will be distributed.

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2018-04-13, 1397/01/24
Ethics committee reference number
IR.SBMU.nftri.Rec.1396.207

Health conditions studied

1

Description of health condition studied
Metabolic syndrom

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
homeostatic model assessment of insulin resistance(HOMA-IR)

Timepoint
Baseline and end of the study

Method of measurement
Calculation : (glucose×Insulin)/22.5

2

Description
homeostatic model assessment of B-cell function(HOMA-B)

Timepoint
Baseline and end of the study

Method of measurement
Calculation

3

Description

Hba1c

Timepoint

Baseline and end of the study

Method of measurement

ion-exchange chromatography

4

Description

Serum glucose

Timepoint

Baseline and end of the study

Method of measurement

Colorimetric analysis method

5

Description

Serum insulin

Timepoint

Baseline and end of the study

Method of measurement

ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each capsule contains 80 mg nanomicelles curcumin. Use once a day for 12 weeks.

Category

Treatment - Other

2

Description

Control group: Each capsule contains yellow colour(E104) and lecithin. Use once a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shohadaye yaft abad hospital and Pars hospital

Full name of responsible person

Golbon Sohrab

Street address

No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2236 0656

Email

golbonsohrab@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

assistant of of Research and Technology of Shahid Beheshti University of Medical Sciences

Street address

No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town

City

tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

golbonsohrab@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zohre Bateni

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2236 0656

Email

zohre.bateni@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2207 7424

Fax

+98 21 2236 0657

Email

golbonsohrab@sbmu.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zohre Bateni

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town

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Province

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Postal code

1981619573

Phone

+98 21 2236 0656

Email

zohre.bateni@yahoo.com

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

Only part of the data is shared, such as the original outcome.

When the data will become available and for how long

The start of the access period is 12 months after printing the results.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The documentation can only be used for more detailed studies in this field.

From where data/document is obtainable

golbonsohrab@sbmu.ac.ir zohre.bateni@yahoo.com

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

The communication will be possible through the electronic mail given in the previous section.

Comments