Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

nanomicielles 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 Henal 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 nanomicielles 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
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

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