

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effects of nanomicielle curcumin on oxidative stress, systemic inflammation, adiponectin in serum and NF-kB in blood mononuclear cells, in patients with metabolic syndrome

Protocol summary

Study aim

Determine the effects of supplementation with nanomicielle curcumin on oxidative stress, systemic inflammation, adiponectin in serum and NF-kB in blood mononuclear cells, 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 Hospital and Pars, 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 fasting blood will be taken from patients . Their height and weight will be .Then, in order to control the confounding factors , they will be randomly assigned to the group receiving nanomicielles curcumin and placebo group.

Participants/Inclusion and exclusion criteria

Patients aged 18-70 years with metabolic syndrome according to NCEP ATP III criteria

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 nanomicielles curcumin daily and patient in control group will receive placebo capsule daily for 12 weeks

Main outcome variables

serum concentration of Malondialdehyde ,Total antioxidant capacity ,high-sensitivity C-reactive protein , adiponectine , Nuclear factor-kB in peripheral blood mononuclear cell

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150815023617N4**
Registration date: **2018-07-03, 1397/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

Registration date

2018-07-03, 1397/04/12

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

The effects of nanomicielle curcumin on oxidative stress, systemic inflammation, adiponectin in serum and NF-kB

in blood mononuclear cells, 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:

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: **23**

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

2018-02-09, 1396/11/20

Ethics committee reference number

IR.SBMU.nftri.Rec.1396.188

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

Adiponectin

Timepoint

Baseline and end of the study

Method of measurement

ELISA method

2

Description

Total Antioxidant Capacity(TAC)

Timepoint

Baseline and end of the study

Method of measurement

Enzymatic colorimetric analysis method

3

Description

Malondialdehyde(MDA)

Timepoint

Baseline and end of the study

Method of measurement

Enzymatic colorimetric analysis method

4

Description

high-sensitivity C-reactive protein(hs-CRP)

Timepoint

Baseline and end of the study

Method of measurement

ELISA method

5

Description

Nuclear factor-κB

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

بیمارستان شهدای یافت آباد

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

2

Recruitment center

Name of recruitment center

Pars hospital

Full name of responsible person

Golbon Sohrab

Street address

No. 7, West Arghavan 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

National Nutrition And Food Technology Research Institute of Iran

Full name of responsible person

Morteza Abdolahi

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

National Nutrition And Food Technology Research Institute of Iran

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
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 2236 0656
Email
golbonsohrab@sbm.ac.ir

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 2236 0656
Email
golbonsohrab@sbm.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

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

From where data/document is obtainable

golbonsohrab@sbm.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