# 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-κB 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**
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:**
**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 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**
بیمارستان شهدای یافت اباد
**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

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Tehran

**Province**
Tehran

**Postal code**
1981619573

**Phone**
+98 21 2236 0656

**Email**
golbonsohrab@sbmu.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

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**City**
Tehran

**Province**
Tehran

**Postal code**
1981619573

**Phone**
+98 21 2236 0656

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

**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**