Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effects of N-acetylcysteine and placebo on metabolic profiles and serum adiponectin levels in patients with metabolic syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of N-acetylcysteine administration on metabolic profiles and serum adiponectin levels in patients with metabolic syndrome.

Design

Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive N-acetylcysteine (n=38) or placebo (n=38).

Settings and conduct

Among patients with metabolic syndrome referred to the Endocrinology Clinic at Baqiyatallah Hospital affiliated to Baqiyatallah Medical Sciences University, Tehran, Iran, 76 patients will be selected. The study will be double blind in which participants and investigators/the assessors of the outcomes are unaware of the study groups and drug and placebo are similar. Fasting blood samples will be taken at baseline and end of the intervention. Intervention period: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with metabolic syndrome; aged 25 to 75 years. Non-inclusion criteria: Patients with infectious, malignant and inflammatory diseases; those taking any antioxidant and/or anti-inflammatory supplements within 16 weeks prior to enrollment in the study; hypersensitivity to the study medication; pregnancy or breastfeeding, diabetes mellitus.

Intervention groups

Intervention group: N-acetylcysteine 600 mg Tablet (Osve Pharmaceutical Co., Tehran, Iran), orally, three times a day, for 12 weeks. Control group: Placebo Tablet (Osve Pharmaceutical Co., Tehran, Iran), three times a day, orally, for 12 weeks.

Main outcome variables

Insulin resistance (primary outcome) and lipid profiles, oxidative damage biomarkers, hs-CRP, and serum adiponectin levels (secondary outcomes)

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N72**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**
Update count: **2**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name
Mohammadreza Sharif
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 5546 3378
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-28, 1399/04/08

Expected recruitment end date

2021-12-24, 1400/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effects of N-acetylcysteine and placebo on metabolic profiles and serum adiponectin levels in patients with metabolic syndrome

Public title
N-acetylcysteine administration in treatment of metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnosed with metabolic syndrome Individuals aged 25-75 years old

Exclusion criteria:
Patients with infectious, malignant and inflammatory diseases Those taking any antioxidant and/or anti-inflammatory supplements within 16 weeks prior to enrollment in the study Hypersensitivity to the study medication Pregnancy or breastfeeding Diabetes mellitus

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 76 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients will be randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Endocrinology Clinic of Baqiyatallah Hospital, who is not involved in the trial and not aware of random sequences, will assign the participants to the numbered bottles of drugs. Drugs and placebos are in the same packaging at the Osve pharmaceutical company. Only the code is written on the packages. Patients and researcher will not know the type of intervention. After analyzing the data, pocket codes will be decoded. Participants and investigators/the assessors of the outcomes are unaware of the study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences

Street address
Baqiyatallah University of Medical Sciences, Molla Sadra Avenue, Tehran

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2020-06-08, 1399/03/19

Ethics committee reference number
IR.BMSU.REC.1399.188

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Insulin resistance

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Calculation using the Homeostasis Model Assessment (HOMA) formula

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
ELISA kit

2

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
High-density lipoprotein (HDL)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Low-density lipoprotein (LDL)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
High-sensitivity C-reactive Protein (hs-CRP)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
ELISA kit

8

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

11

Description
Adiponectin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
ELISA kit

Intervention groups

1

Description
Intervention group: N-acetylcysteine 600 mg Tablet (Osve Pharmaceutical Co., Tehran, Iran), orally, three times a day, for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Placebo Tablet (Osve Pharmaceutical Co., Tehran, Iran), three times a day, orally, for 12 weeks.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology Clinic of Baqiyatallah Hospital

Full name of responsible person
Dr. Yunes Panahi

Street address
Baqiyatallah University of Medical Sciences, Molla Sadra Avenue, Tehran

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yunespanahi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
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Alishiri.gh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Dr. Yunes Panahi

Position
Academic Researcher

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available