

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 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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ostadmohammadi-vr@kaums.ac.ir

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

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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

Dr. Gholamhosein Alishiri

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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