Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effects of N-Acetylcysteine on senescence of visceral adipose tissue, anthropometric indices, serum levels of lipid profile, glycemic indices, and inflammatory factors in obese adults

Protocol summary

Study aim

Determine the effects of N-Acetylcysteine (NAC) on senescence of visceral adipose tissue, anthropometric indices, serum levels of lipid profile, glycemic indices, and inflammatory factors in obese adults

Design

A parallel randomized block clinical trial (blocks of 4) stratified by age and body mass index, phase 3, double-blind clinical trial on 50 obese adults for 4 weeks.

Settings and conduct

This study will be conducted in the surgery and obesity clinic of Modarres Hospital on 50 obese adults. The study will be conducted in a double-blind manner with a control group. Due to the double-blindness of the study, before the start of the study, the sets of cans containing capsules will be prepared by someone other than the researcher, and the placebo will be similar in appearance to the intervention group. The intervention group will receive 600 mg N-acetylcysteine per day and the control group will receive 600 mg placebo per day for 4 weeks. At the beginning and after 4 weeks, the different effects of the intervention on these people are examined and compared.

Participants/Inclusion and exclusion criteria

People with obesity with a body mass index (BMI) greater than or equal to 30 kg/m2, Age over 25 years, Non-pregnant, Non-lactating, Not suffering from chronic and acute inflammatory, and infectious diseases, Not suffering from high blood pressure and vascular diseases, Not receiving alcohol and smoking, Not participating in other clinical trial studies at the same time as the present study, Not receiving weight loss and antioxidant drugs and supplements in the last three months.

Intervention groups

The intervention and control groups will receive 600 mg of N-acetylcysteine supplement and placebo 4 weeks before sleeve surgery, respectively.

Main outcome variables

Weight, beta-galactosidase activity, triglyceride, glucose, total cholesterol, and interleukin-6.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220727055563N1**
Registration date: **2022-08-19, 1401/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-19, 1401/05/28**
Update count: **0**

Registration date

2022-08-19, 1401/05/28

Registrant information

Name

Hamid Zand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 7424

Email address

hamidzand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-11, 1401/05/20

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of N-Acetylcysteine on senescence of visceral adipose tissue, anthropometric indices, serum levels of lipid profile, glycemic indices, and inflammatory factors in obese adults

Public title

Effects of N-Acetylcysteine on senescence of visceral adipose tissue, anthropometric indices, serum levels of lipid profile, glycemic indices, and inflammatory factors in obese adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obese people with a body mass index greater than or equal to 30 kg/m2. Age over 25 years Non-pregnant Non-lactating Not suffering from chronic and acute inflammatory, and infectious diseases Not suffering from high blood pressure and vascular diseases Not receiving alcohol and smoking

Exclusion criteria:

Receiving weight loss and antioxidant drugs and supplements in the last three months Participating in other clinical trial studies at the same time as the present study. Adherence to weight loss diets during the last three months. History of gastrointestinal or bariatric surgeries.

Age

From **25 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used as Stratified Randomization using the Permuted block randomization method with quadruple and double blocks. According to the sample size of 70 that has been determined, the quadruple and double blocks will be produced using the software. In the Stratified Randomization method, age and BMI will be used as layers. In order to apply concealment in the randomization process, unique codes will be used on medicine boxes, and the desired code will be generated by the software. As each person enters the study based on the generated sequence, the drug package in which the desired code is recorded will be assigned to the person, and therefore, before choosing the person, no one will be aware of the type of treatment that the person will receive. Also, the random sequence generated during the study will be immune to prediction.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. Participants will be divided into two groups receiving N-Acetylcysteine supplementation and the placebo group. Due to the double-blindness of the study, before starting the study, sets of cans containing N-Acetylcysteine supplementation will be prepared by someone other than the researcher, and the placebo will be similar in appearance to N-Acetylcysteine, so that the researcher does not know the type of treatment received by each group. In addition, the researcher in the evaluation phase of the desired outcomes (anthropometric measurements, blood tests, and biochemistry) from the allocation of participants in each of the groups (intervention and control group) until after the end of the intervention period will be uninformed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of National Nutrition & Food Technology Research Institute

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1401.029

Health conditions studied

1

Description of health condition studied

Obesity adults

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description
Weight
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Seca scale

2

Description
Beta-galactosidase activity
Timepoint
The end of week 4
Method of measurement
Using PCR (polymerase chain reaction)

Secondary outcomes

1

Description
Waist circumference
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Measuring tape

2

Description
Serum cholesterol, triglyceride, LDL and HDL levels
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Blood sampling and measurement by ELISA method

3

Description
Serum glucose levels
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Blood sampling and measurement by ELISA method

4

Description
Serum insulin levels
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Blood sampling and measurement by ELISA method

5

Description
C-reactive protein (CRP) level
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Blood sampling and measurement by ELISA method

6

Description
Body mass index
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Calculation

7

Description
Interleukin-6
Timepoint
At the beginning of the study and at the end of week 4
Method of measurement
Blood sampling and measurement by ELISA method

Intervention groups

1

Description
Intervention group: Daily 600 mg of NAC supplement prepared by Osvah Pharmaceutical Company of Iran for 4 weeks
Category
Treatment - Drugs

2

Description
Control group: Daily 600 mg maltodextrin supplement prepared by Karen Pharmaceutical Company of Iran for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Nasser Malekpour
Street address
Saadat Abad intersection, Yadgar Imam highway, Tehran.
City
Tehran
Province
Tehran

Postal code
1998734383
Phone
+98 21 2207 4087
Email
modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi, Vice President of Research and Technology, Shahid Beheshti University
Street address
Building No. 2 - 5th floor, Shahid Arabi St., Yemen St., Shahid Chamran highway, Tehran.
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1985717443
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Email
info@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
Hamid Zand
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments
-