# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Effects of N-acetylcysteine on the expression of UCP1, didinase type 2 and 3, as well as thyroid hormone receptors alpha and beta in visceral adipose tissue of obese adults

## Protocol summary

**Study aim**

Determining the effects of N-acetylcysteine on the expression of UCP1, didinase type 2 and 3, as well as thyroid hormone receptors alpha and beta in visceral adipose tissue of obese adults

**Design**

A clinical trial with a control group, with parallel groups, randomized, phase 3, double-blind on 50 obese adults. Random allocation will be used as Stratified Randomization using the Permuted block randomization method with quadruple and double blocks.

**Settings and conduct**

This study will be conducted in the surgery and obesity clinic of Imam Hussein Hospital (Tehran, Iran) 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 6 weeks. At the beginning and after 6 weeks, the different effects of the intervention on these people are examined and compared.

**Participants/Inclusion and exclusion criteria**

Entry requirements: 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 6 weeks before sleeve surgery, respectively.

**Main outcome variables**

Weight, expression of UCP1, didinase type 2 and 3, thyroid hormone receptors alpha and beta

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220727055563N2**
Registration date: **2023-07-01, 1402/04/10**
Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**
Update count: **0**

**Registration date**

2023-07-01, 1402/04/10

**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**

2023-07-20, 1402/04/29

**Expected recruitment end date**

2023-09-11, 1402/06/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of N-acetylcysteine on the expression of UCP1, didinase type 2 and 3, as well as thyroid hormone receptors alpha and beta in visceral adipose tissue of obese adults

**Public title**

Effects of N-acetylcysteine on the expression of UCP1, didinase type 2 and 3, as well as thyroid hormone receptors alpha and beta in visceral adipose tissue of 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 and 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 to **60 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 (measurements of biochemistry and related gene expression) 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**

2023-06-12, 1402/03/22

**Ethics committee reference number**

IR.SBMU.NNFTRI.REC.1402.012

## Health conditions studied

### 1

**Description of health condition studied**

Obesity adults

**ICD-10 code**

E66
**ICD-10 code description**
Overweight and obesity

## Primary outcomes

### 1

**Description**
Expression of UCP1 genes
**Timepoint**
At the end of week 6
**Method of measurement**
Using PCR (polymerase chain reaction)

## Secondary outcomes

### 1

**Description**
Expression of didinase type 2 and 3 genes
**Timepoint**
The end of week 6
**Method of measurement**
Using PCR (polymerase chain reaction)

### 2

**Description**
Expression of alpha and beta thyroid hormone receptor genes
**Timepoint**
The end of week 6
**Method of measurement**
Using PCR (polymerase chain reaction)

### 3

**Description**
Serum level of thyroid hormones (TSH, T3 and T4)
**Timepoint**
At the beginning of the study and at the end of week 6
**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 6 weeks
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Daily 600 mg maltodextrin supplement prepared by Karen Pharmaceutical Company of Iran for 6 weeks
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Hossein Hospital
**Full name of responsible person**
Hamid Zand
**Street address**
Imam Hossein (AS) Medical Research Training Center, Shahid Madani St, Tehran.
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**Province**
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1998734383
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info@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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**Phone**
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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**
Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Biochemistry
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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

**Contact**
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**Latest degree**
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hamidzand@gmail.com

## 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**
Information on the main implications can be shared at the end of the study.
**When the data will become available and for how long**
The access period will be 6 months after the results are published.
**To whom data/document is available**
The data from this study will be available only to researchers working in academic and scientific institutions.
**Under which criteria data/document could be used**
6 months after the publication of the articles obtained from the data of this project, at the request of the person in charge of the project and his consent, the study data can be made available to researchers.
**From where data/document is obtainable**

-Applicants can contact the responsible author via email or the following mailing address to obtain the required data. Postal address:Tehran, Farahzadi Blvd., Tree St., Hafezi Alley, Faculty of Nutrition Sciences, Cellular-Molecular Group. Dr. Hamid Zand, email: hamidzand@gmail.com

**What processes are involved for a request to access data/document**

Applicants will be able to access the study data by sending an email to the responsible author within a maximum of one week.

**Comments**