

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparing the effects of N-acetylcysteine administration and placebo on clinical status and metabolic profiles in overweight or obese women with fibrocystic changes of breast

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of N-acetylcysteine administration on clinical status and metabolic profiles in overweight or obese women with fibrocystic changes of breast.

##### Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive N-acetylcysteine (n=37) or placebo (n=37).

##### Settings and conduct

Among overweight or obese women with fibrocystic changes of breast who are referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 74 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Drugs and placebos are similar. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. intervention period: 12 weeks

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-45 years diagnosed with fibrocystic breast disease, having moderate or severe cyclic mastalgia, BMI  $\geq 25$ . Exclusion criteria: Malignant breast diseases, taking medicines for reducing pain (such as danazol, tamoxifen, bromocriptine) over the past three months, menopause women, pregnant or breastfeeding women, psychological diseases, Unwillingness to cooperate

##### Intervention groups

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

##### Main outcome variables

hs-CRP (primary outcome) and Breast Pain Severity, biomarkers of oxidative stress, parameters of mental

health, glucose and lipid metabolism indices (secondary outcomes)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N69**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

##### Registration date

2020-04-11, 1399/01/23

##### Registrant information

##### Name

Mohammadreza Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5546 3378

##### Email address

ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-02-02, 1398/11/13

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparing the effects of N-acetylcysteine administration and placebo on clinical status and metabolic profiles in overweight or obese women with fibrocystic changes of breast

**Public title**  
Effects of N-acetylcysteine administration in the treatment of fibrocystic changes of breast

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients aged 18-45 years women diagnosed with fibrocystic breast disease having moderate or severe cyclic mastalgia BMI  $\geq 25$   
**Exclusion criteria:**  
 Malignant breast diseases Taking medicines for reducing pain (such as danazol, tamoxifen, bromocriptine) over the past three months Menopause women Pregnant or breastfeeding women Psychological diseases Unwillingness to cooperate

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **74**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 74 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 general surgery clinic, who is not involved in the trial and not aware of random sequences, will be assigned 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 drug.

After analyzing the data, pocket codes will be decoded. Participants, investigators or 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 Kashan University of Medical Sciences  
**Street address**  
 Ghotbe Ravandi Boulevard, Kashan  
**City**  
 Kashan  
**Province**  
 Isfahan  
**Postal code**  
 8115187159

**Approval date**  
2020-02-01, 1398/11/12

**Ethics committee reference number**  
IR.KAUMS.MEDNT.REC.1398.124

**Health conditions studied**

**1**

**Description of health condition studied**  
Breast fibrocystic disease

**ICD-10 code**  
N60

**ICD-10 code description**  
Benign mammary dysplasia

**Primary outcomes**

**1**

**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

**Secondary outcomes**

## **1**

### **Description**

Breast Pain Severity

### **Timepoint**

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

### **Method of measurement**

Visual analogue scale 0-10

## **2**

### **Description**

Malondialdehyde

### **Timepoint**

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

### **Method of measurement**

Spectrophotometry

## **3**

### **Description**

Glutathione

### **Timepoint**

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

### **Method of measurement**

Spectrophotometry

## **4**

### **Description**

Total antioxidant capacity

### **Timepoint**

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

### **Method of measurement**

Spectrophotometry

## **5**

### **Description**

Triglycerides

### **Timepoint**

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

### **Method of measurement**

Enzymatic kit

## **6**

### **Description**

Total cholesterol

### **Timepoint**

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

### **Method of measurement**

Enzymatic kit

## **7**

### **Description**

High-density lipoprotein (HDL) cholesterol

## **Timepoint**

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

## **Method of measurement**

Enzymatic kit

## **8**

### **Description**

Insulin

### **Timepoint**

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

### **Method of measurement**

Elisa kit

## **9**

### **Description**

Insulin resistance

### **Timepoint**

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

### **Method of measurement**

Calculation using Homeostatic model assessment of insulin resistance formula

## **10**

### **Description**

Depression score on Beck Depression Inventory

### **Timepoint**

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

### **Method of measurement**

Questionnaire

## **11**

### **Description**

Anxiety score on Beck Anxiety Inventory

### **Timepoint**

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

### **Method of measurement**

Questionnaire

## **12**

### **Description**

Sleep Quality score on Pittsburgh Sleep Quality Index

### **Timepoint**

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

### **Method of measurement**

Questionnaire

## **Intervention groups**

## **1**

### **Description**

Intervention group: Tab N-acetylcysteine 600 mg three

times a day (Osve Pharmaceutical Co., Tehran, Iran), for 12 weeks orally.

**Category**

Treatment - Drugs

**2**

**Description**

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

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Beheshti Clinic

**Full name of responsible person**

Dr. Aliakbar Salmani

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5554 0026

**Email**

salmani.aliakbar@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Hamidreza Banafshe

**Street address**

Ghotbe Ravandi Boulevard, Kashan

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banafshe-h@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Aliakbar Salmani

**Position**

Resident of general surgery

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Aliakbar Salmani

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Aliakbar Salmani

**Position**

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**Email**

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## 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