

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of N-acetylcysteine on the quality of life, anxiety and antioxidant indexes of patients with cardiovascular disease.

Protocol summary

Summary

Purposes; the effect of N-acetylcysteine on quality of life, anxiety and antioxidant properties of cardiovascular patients. Design; this study is triple-blind clinical trial will that be done on 120 patients (in two groups: 60 patients in the intervention group and 60 patients in the control group). Procedures; before starting treatment, quality of life and anxiety will evaluate using the MacNew and Spillberger questionnaires in two groups. Intervention; the intervention and control groups will orally give with 600 mg n-acetyl cysteine and 600 mg placebo (respectively) twice a day for 30 days. The main outcome variables; quality of life and anxiety properties will assessed via the MacNew and Spillberger questionnaires. In addition, for evaluating the antioxidant biomarkers fasting blood sample will be taken from all three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121425526N1**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Hamzehe Najafia

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3222 2567

Email address

hamzehe_najafy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of N-acetylcysteine on the quality of life, anxiety and antioxidant indexes of patients with cardiovascular disease.

Public title

Effects of N-acetylcysteine on the quality of life, anxiety and antioxidant indexes of patients with cardiovascular disease.

Purpose

Supportive

Inclusion/Exclusion criteria

Criteria 1. patients with acute coronary syndrome, coronary artery disease, the treating physician to confirm the diagnosis reached. 2 people (women and men) aged 65-18 years able to read and write their own. 3. People who have the full consent to participate in research. 4. People who have a history of these-acetylcysteine orally, by injection or inhalation during the first months of treatment have not. 5 people without a history of hypersensitivity reactions after taking it

approved acetylcysteine 6. The people who received both medications or substances with antioxidant effects as vitamin E, A or vitamin A, E, vitamin C, at least one month before the quake 7. People with a history of anti-anxiety drugs, have. 8 people aged 65-18 years. 9. The lack of disease HCV +, HBSAg +, HIV +, diabetes, kidney disease, 10 of pregnancy Exclusion criteria (1) patients who can not understand the questions or did not have the time and location aware. 2. Patients in the study were dissatisfied. 3. Patients who withdrew during the study. 4. People who do not consume drugs. 5 people who died during the study. 6. Individuals involved in the research program to improve the quality of life or reduce anxiety, such as health promotion, and rehabilitation and so on are. 7 people in the business week by experts and researchers to track the phone call not to participate or not. 8. ejection fraction less than 40% for the echocardiogram

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Lorestan University of Medical Sciences

Street address

Lorestan university of medical sciences, Khorramabad. Iran

City

Khorramadad

Postal code

11569689

Approval date

2015-11-08, 1394/08/17

Ethics committee reference number

lums.rec.1394.40

Health conditions studied**1****Description of health condition studied**

cardiovascular disease

ICD-10 code

120-125

ICD-10 code description

Ischaemic heart diseases

2**Description of health condition studied**

cardiovascular disease

ICD-10 code

120-125

ICD-10 code description

Ischaemic heart diseases

Primary outcomes**1****Description**

quality of life

Timepoint

After and before of the intervention

Method of measurement

MacNew Questionnaire

2**Description**

anxiety level

Timepoint

After and before of the intervention

Method of measurement

Spielberger Questionnaire

3**Description**

blood antioxidant biomarker indexes

Timepoint

After and before of the intervention

Method of measurement

biochemical assesing

Secondary outcomes**1****Description**

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group 1: oral administrations of 600MG N-acetyl cysteine (Avicenna Pharmacy Co.) twice a day for 30 days.

Category

Treatment - Drugs

2

Description

Control group: without drug treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khominia hospital

Full name of responsible person

Hamzehe Najafi

Street address

Lorests-n-Poldokhtar- koye basijian

City

Poldokhtar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Shahin Raofi

Street address

Khorramabad, Lorestan, Iran

City

Khoramabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lorestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Hamzehe Najafia

Position

Master student

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Hmzeh Najafy

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty