Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
Lorestsn-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
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Hamzehe Najafia
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Emam khomini hospital of Poldokhtar
Full name of responsible person
Hmzeh Najafy
Position
nurse
Other areas of specialty/work
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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