Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Effect of N-acetylcysteine as adjunct therapy versus placebo on clinical outcomes and serum levels of oxidative stress biomarkers in patients with systolic heart failure: a double blind clinical trial

Protocol summary

Study aim

To assess the effect of N-acetylcysteine as adjunct therapy versus placebo on clinical outcomes and serum levels of oxidative stress biomarkers in patients with systolic heart failure

Design

This is a double-blind randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with systolic heart failure will refer to Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 80 years, Systolic heart failure, Constant drug treatment for heart failure for at least 2 months, Stable clinical and hemodynamic status, Exclusion criteria: Pregnancy or breastfeeding, Concomitant chronic liver, kidney or respiratory diseases, History of myocardial infarction

Intervention groups

Intervention group: Routine treatment plus adjunct therapy with N-acetylcysteine tablet 600 mg (manufactured by Hakim Pharmaceutical Company) every 12 hours for 3 months Control group: Routine treatment plus adjunct therapy with placebo (manufactured by Hakim Pharmaceutical Company) every 12 hours for 3 months

Main outcome variables

Left and right ventricular ejection fraction, left and right ventricular Tei-index, left and right ventricular strain, the activity of catalase enzyme, the activity of superoxide dismutase enzyme, the activity of peroxidase enzyme, the activity of malondialdehyde enzyme, the activity of total antioxidant capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N333**
Registration date: **2020-01-11, 1398/10/21**
Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**
Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of N-acetylcysteine as adjunct therapy versus placebo on clinical outcomes and serum levels of oxidative stress biomarkers in patients with systolic heart failure: a double blind clinical trial

Public title
Effect of N-acetylcysteine as adjunct therapy versus placebo on clinical outcomes and serum levels of oxidative stress biomarkers in patients with systolic heart failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 80 years, Systolic heart failure, Constant drug treatment for heart failure for at least 2 months, Stable clinical and hemodynamic status,
Exclusion criteria:
Pregnancy or breastfeeding, Concomitant chronic liver, kidney or respiratory diseases, History of myocardial infarction
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple-blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2019-12-07, 1398/09/16
Ethics committee reference number
IR.UMSHA.REC.1398.738

Health conditions studied

1

Description of health condition studied
Systolic heart failure
ICD-10 code
I50.2
ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
Left and right ventricular ejection fraction
Timepoint
Bfore and 3 months after the intervention
Method of measurement
By echocardiography

2

Description
Left and right ventricular Tei-index
Timepoint

Bfore and 3 months after the intervention

Method of measurement

By echocardiography

3

Description

Left and right ventricular strain

Timepoint

Bfore and 3 months after the intervention

Method of measurement

By echocardiography

4

Description

Activity of catalase enzyme

Timepoint

Before and 3 months after the intervention

Method of measurement

By in vitro serum analysis

5

Description

Activity of superoxide dismutase enzyme

Timepoint

Before and 3 months after the intervention

Method of measurement

By in vitro serum analysis

6

Description

Activity of peroxidase enzyme

Timepoint

Before and 3 months after the intervention

Method of measurement

By in vitro serum analysis

7

Description

Activity of malondialdehyde enzyme

Timepoint

Before and 3 months after the intervention

Method of measurement

By in vitro serum analysis

8

Description

Activity of total antioxidant capacity

Timepoint

Before and 3 months after the intervention

Method of measurement

By in vitro serum analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus adjunct therapy with N-acetylcysteine tablet 600 mg (manufactured by Hakim Pharmaceutical Company) every 12 hours for 3 months

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus adjunct therapy with placebo (manufactured by Hakim Pharmaceutical Company) every 12 hours for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Dr. Maryam Mehrpooya

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Maryam Mehrpooya

Position

Clinical Phamacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree

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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