

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect and safety of nanocurcumin on patients with heart failure reduced EF (HFrEF)

Protocol summary

Study aim

The effect of nanocurcumin on IL-6 and NT-proBNP reduction in patients with heart failure reduced EF

Design

It is a double-blind clinical trial, phase 3, with a placebo, performed on 60 patients with reduced EF heart failure. The permutation block method will be used for the randomization and patient allocation.

Settings and conduct

Heart Department of Baqiyatallah Hospital

Participants/Inclusion and exclusion criteria

patients with heart failure with reduced EF; no history of the rheumatologic disease; no active infection; no acute kidney injury Signing an informed consent form.

Intervention groups

30 patients in the intervention group will receive a nanocurcumin supplement at a dose of 40mg twice daily with an standard regimen. 30 patients in the control group will receive a placebo twice a day with an standard regimen.

Main outcome variables

Interleukin 6; NT-ProBNP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221007056110N1**

Registration date: **2022-10-25, 1401/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-25, 1401/08/03**

Update count: **0**

Registration date

2022-10-25, 1401/08/03

Registrant information

Name

Emadoddin Hosseinjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 23601

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e.hosseinjani@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect and safety of nanocurcumin on patients with heart failure reduced EF (HFrEF)

Public title

Effect of nanocurcumin in heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with reduced EF heart failure Signing an informed consent form

Exclusion criteria:

No history of rheumatologic disease No active infection No acute kidney injury

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted blocks method using the site <https://www.sealedenvelope.com> will be used. Each block has six components. The form of the blocks can be as follows for example: [ABAABAB], [BBABAA], [BABABA], Codes A and B are randomly assigned to intervention and control groups. The site randomly selects 11 blocks from all possible six-block forms to include all the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the DUE unit expert only has complete information about the type of drug received (placebo or nanocurcumin supplement). This person plays no role in the administration, treatment evaluation, and data analysis. According to the codes, the patients who fulfill the inclusion criteria are randomly assigned to one of the groups by the DUE unit expert. The pills are then given to the researchers who are unaware of the content of the codes and the tablets type and then prescribed. The placebo pill is very similar to the nanocurcumin pill and contains the same ingredients except for the active ingredient. Therefore, patients and clinical caregivers can't distinguish pills from each other.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethice Committee of Baqiyatallah University of Medical Sciences

Street address

Sheikh Bahaie South Street, Mulla Sadra Street, Vanak Square, Tehran, IRAN.

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2022-09-05, 1401/06/14

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.045

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

heart failure reduced EF

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

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

Interleukin 6

Timepoint

At the beginning of the study and after receiving the last dose of nanocurcumin

Method of measurement

Laboratory tests

2**Description**

NT-proBNP

Timepoint

At the beginning of the study and after receiving the last dose of nanocurcumin

Method of measurement

Laboratory tests

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

serum creatinine

Timepoint

At the beginning of the study and after receiving the last dose of nanocurcumin

Method of measurement

laboratory tests

2**Description**

WBC count

Timepoint

En At the beginning of the study and after receiving the

last dose of nanocurcumin
Method of measurement
laboratory tests

3

Description
ALT

Timepoint
At the beginning of the study and after receiving the last dose of nanocurcumin

Method of measurement
laboratory tests

4

Description
AST

Timepoint
At the beginning of the study and after receiving the last dose of nanocurcumin

Method of measurement
laboratory tests

Intervention groups

1

Description
Intervention group: 30 patients with HREF which are admitted with congestion and decompensated symptoms will receive 40 mg nanocurcumin capsule twice a day for 7 days and standard therapy will be continued.

Category
Treatment - Drugs

2

Description
Control group: 30 patients with HREF which are admitted with congestion and decompensated symptoms will receive 40 mg placebo capsule similar to original drug twice a day for 7 days and standard therapy will be continued.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Emadoddin Hosseini
Street address
Vanak Square, Mulla Sadra Street, after Sheikh Bahayi, Baqiyatallah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology
Street address
Venk Square, Mulla Sadra St., Sheikh Bahai St., Baqiyatullah University, 3rd Floor, Research and Technology Vice-Chancellor
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Phone
+98 21 8755 5250
Email
R.bmsu@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Emadoddin Hosseini
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work

Cardiology

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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