

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of garlic on quality of life and improvement of cardiac function in patients with heart failure

Protocol summary

Study aim

Determining the effect of garlic pills on quality of life and improving overall heart function and treatment of patients with heart failure

Design

The present study is a randomized clinical trial with a control group receiving placebo and three-blind. The researcher or the person making the measurements, the patients and the data analyzer will be unaware of the drug code and placebo. The study population includes men and women with class III and II heart failure who referred to Isfahan reference offices and met the inclusion criteria.

Settings and conduct

From patients with heart failure referred to Isfahan reference offices, men and women who were in class III and II of the New York Heart Association and are over the age of 18 and have inclusion criteria will be easily selected.

Participants/Inclusion and exclusion criteria

Having heart failure Unwillingness to continue the cooperation of each unit of research during the study. Therapeutic use of any natural substances and plants during treatment. Discontinuation of the drug for any cause or complication or change in the main drugs.

Intervention groups

Patients given garlic medicine

Main outcome variables

Provide herbal therapy based on findings to evaluate and manage the patient's activity and shortness of breath and changes in heart function as measured by echo and blood tests in patients with heart failure Tests include CBC, PT, ptt, cholesterol, TG, LDL, HDL, FBS, TSH, BUN, Cr

General information

Reason for update

Acronym

garlic

IRCT registration information

IRCT registration number: **IRCT20181121041715N1**
Registration date: **2020-08-18, 1399/05/28**
Registration timing: **prospective**

Last update: **2020-08-18, 1399/05/28**

Update count: **0**

Registration date

2020-08-18, 1399/05/28

Registrant information

Name

sima Azish

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3611 5209

Email address

sima.azish@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of garlic on quality of life and improvement of cardiac function in patients with heart failure

Public title

The effect of garlic on quality of life and improvement of cardiac function in patients with heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with heart failure in the age range of 18 years and above. For patients diagnosed at least 3 months in advance according to the New York Heart Association classification in Class III and II Their discharge fraction is reported to be less than 45%. Receiving common and standard medications for heart failure. Women should not be pregnant or breastfeeding and should use safe methods of contraception at reproductive age Do not suffer from mental illnesses, thyroid, anemia, obstructive pulmonary disease, malignancies, hepatitis, kidney and liver failure, uncontrolled diabetes and uncontrolled hypertension, gastrointestinal diseases. The patient's blood pressure is below 100/180.

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

After that, the eligible patients are listed and based on block randomization, they are divided into two groups of intervention and control. In the randomized block method, the number of each block is considered to be 4 people. . For example, BABA permutation, so the first person who is eligible and enters the study receives the envelope b or placebo of the second person a or medicine and the third person b and the fourth person a

Blinding (investigator's opinion)

Triple blinded

Blinding description

The present study is a randomized clinical trial with a control group receiving placebo and three-blind. The researcher or the person making the measurements, the patients and the data analyzer will be unaware of the drug code and placebo. .

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan Medical School

Street address

Salman Farsi St. Chamran Heart Hospital

City

esfahan

Province

Isfahan

Postal code

8166173414

Approval date

2019-09-29, 1398/07/07

Ethics committee reference number

IR.MUI.MED.REC.1398.273

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

EF

Timepoint

EF-40

Method of measurement

ECKO

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The patient who receives the placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

chamran hospital

Full name of responsible person

davood shafiee

Street address

Salman Farsi St. Chamran Heart Hospital

City

esfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3261 1406

Email

d.shafie87@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

davood shafiee

Street address

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Email

d.shafie87@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

10

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

Esfahan University of Medical Sciences

Full name of responsible person

sima azish

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

davood shafiee

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

resident

Latest degree

Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results are published and communicated to everyone

When the data will become available and for how long

2020

To whom data/document is available

The results are published and communicated to everyone

Under which criteria data/document could be used

heart Failure

From where data/document is obtainable

dr shafiee

What processes are involved for a request to access data/document

Official letter to Dr. Shafiee

Comments