

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of lycopene supplementation on lipid profile and flow mediated dilatation index and blood pressure in patients with ischemic heart failure

Protocol summary

Study aim

The effect of lycopene supplementation on lipid profile and flow mediated dilatation index and blood pressure in patients with ischemic heart failure

Design

Clinical trial with control group with parallel groups, phase 2-3 on 50 patients

Settings and conduct

This study is performed in Chamran Hospital in Isfahan. Patients will be treated with lycopene or placebo tablets, and blood pressure and flow mediated dilatation index will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the person's desire to participate in the project, heart failure due to myocardial infarction with a ejection fraction below 40%, having a body mass index between 18.5 to 30. Exclusion criteria: suffering from autoimmune, respiratory, acute phase of cancer or surgery, infectious and liver diseases and diabetes, having other heart diseases, taking corticosteroid and immunosuppressive drugs, consumption of supplements with antioxidant properties

Intervention groups

Intervention group: Patients in this group will receive lycopene tablets made by Vitabiotics company once a day for 8 weeks. Variables will be measured before and after taking the medication. Control group: Patients in this group will receive placebo tablets containing starch once a day for 8 weeks. Variables will be measured before and after taking the medication.

Main outcome variables

Blood pressure and flow mediated dilatation index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N4**

Registration date: **2021-09-02, 1400/06/11**

Registration timing: **prospective**

Last update: **2021-09-02, 1400/06/11**

Update count: **0**

Registration date

2021-09-02, 1400/06/11

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2021-10-06, 1400/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lycopene supplementation on lipid profile and flow mediated dilatation index and blood pressure in

patients with ischemic heart failure

Public title

Lycopene and flow mediated dilatation index and blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The person's desire to participate in the project Heart failure due to myocardial infarction with a ejection fraction below 40% Having a body mass index between 18.5 to 30

Exclusion criteria:

Suffering from autoimmune, respiratory, acute phase of cancer or surgery, infectious and liver diseases and diabetes Having other heart diseases Taking corticosteroid and immunosuppressive drugs Consumption of supplements with antioxidant properties

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Experiment participants as well as the facilitator will not be informed of how the two groups are divided. A person who has no role in patient selection and data analysis encodes placebo and drug tablets and puts them in a box, and these boxes, each with a code, are given to patients by the project manager who does not know how to code. After the analysis, patient coding will be defined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical

Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-12-26, 1399/10/06

Ethics committee reference number

IR.MUI.MED.REC.1399.856

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

Flow mediated dilatation index

Timepoint

Before and 8 weeks after interventions

Method of measurement

Ultrasound

2

Description

Blood pressure

Timepoint

Before and 8 weeks after interventions

Method of measurement

Blood pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive lycopene tablets made by Vitabiotics company once a day for 8 weeks. Variables will be measured before and after taking the medication.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive placebo tablets containing starch once a day for 8 weeks. Variables will be measured before and after taking the medication.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Masoumeh Sadeghi

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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8174673461

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+98 31 3668 0042

Email

parsa.alinezhad85@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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Phone

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haghjoo.sh@med.mui.ac.ir

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

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

Esfahan University of Medical Sciences

Full name of responsible person

Masoumeh Sadeghi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments