Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Isfehan
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
City
Isfahan
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Isfehan
Postal code
8174673461
Phone
+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
City
Isfahan
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Postal code
8174673118
Phone
+98 31 3668 0048
Email
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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Full name of responsible person
Masoumeh Sadeghi

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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