Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Lycopene on the expression level of Mir-210, Antioxidant factors and apolipoproteins in patients with ischemic heart failure referring to Isfahan Chamran hospital: A randomized Clinical Trial

Protocol summary

Study aim

Effect of lycopene supplements on micro RNA-210 expression, EF levels, paraoxonase enzyme, antioxidant capacity, lipid profile, and LDL oxidation in heart failure patients

Design

Two-arm, randomized, triple-blind clinical trial was conducted on 48 patients with an intervention group (receiving lycopene tablets) and a control group (receiving placebo).

Settings and conduct

Chamran Heart Hospital in Isfahan started its operation in March 2024.The clinical trial is a randomized controlled trial with three groups (investigator, executor, and patient) and involves taking about 50 cc of blood from the patient through venipuncture and performing echocardiography.

Participants/Inclusion and exclusion criteria

Male patients aged 40-70 y/0 with ischemic heart failure and ejection fraction ventricular contraction of 20-40 are eligible to participate. Patients with various malignancies, diabetes, autoimmune diseases, history of organ transplant or use of immunosuppressive drugs, respiratory diseases, history of stroke, atrial fibrillation and other cardiac rhythm disorders, recent surgery, active viral or inflammatory diseases, anemia with hemoglobin less than 10 grams per deciliter, body mass index less than 17 and greater than 30, malabsorption, patients who have used any antioxidant within one month prior to the start of the intervention, and tobacco use are excluded from the study.

Intervention groups

Intervention group: daily intake of 25 mg lycopene for 8 weeks. Control group receives placebo for 8 weeks.

Main outcome variables

The effect of consuming lycopene supplements on the expression level of microRNA-210 in plasma; paraoxonase enzyme activity; total antioxidant capacity; lipid profile; and oxidation of LDL and Ejection Fraction in patients with heart failure

General information

Reason for update

Acronym

Miracle

IRCT registration information

IRCT registration number: **IRCT20200914048711N1**
Registration date: **2024-03-03, 1402/12/13**
Registration timing: **prospective**

Last update: **2024-03-03, 1402/12/13**
Update count: **0**

Registration date

2024-03-03, 1402/12/13

Registrant information

Name

Laila Rejali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 8841

Email address

lailarejali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-10, 1402/12/20

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Lycopene on the expression level of Mir-210, Antioxidant factors and apolipoproteins in patients with ischemic heart failure referring to Isfahan Chamran hospital: A randomized Clinical Trial

Public title

The effect of Lycopene on the expression level of Mir-210, Antioxidant factors and apolipoproteins in patients with ischemic heart failure referring to Isfahan Chamran hospital: A randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ischemic heart failure Age: 40 -70 years olds Ejection Fraction: 20 - 40

Exclusion criteria:

Patients with cancer, nephrotic diseases, diabetes, autoimmune diseases, organ transplantation, immunosuppressive drugs, bronchial diseases, stroke, arrhythmia, late surgery, active viral infection, active internal hemorrage, anemia with Hb<10g/dl Smoking

Age

From **40 years** old to **70 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number tables have been used in statistics for tasks such as selected random samples. This was much more effective than manually selecting the random samples. If carefully prepared, the filtering and testing processes remove any noticeable bias or asymmetry from the hardware-generated original numbers so that such tables provide the most "reliable" random numbers available to the casual user. Note that any published (or otherwise accessible) random data table is unsuitable for cryptographic purposes since the accessibility of the numbers makes them effectively predictable, and hence their effect on a cryptosystem is also predictable. By way of contrast, genuinely random numbers that are only accessible to the intended encoder and decoder allow literally unbreakable encryption of a similar or lesser amount of meaningful data (using a simple exclusive OR operation) in a method known as the one-time pad, which has often insurmountable problems that are barriers to implementing this method correctly

Blinding (investigator's opinion)

Triple blinded

Blinding description

Triple-blind (i.e., triple-masking) studies are randomized experiments in which the treatment or intervention is unknown to (a) the research participant, (b) the individual(s) who administer the treatment or intervention, and (c) the individual(s) who assess the outcomes. The terms blind and masking are synonymous; both terms describe methods that heslp to ensure that individuals do not know which treatment or intervention is being administered. The purpose of triple-blinding procedures is to reduce assessment bias and to increase the accuracy and objectivity of clinical outcomes

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Falavarjan

Street address

Falavarjan, University square, University Blvd

City

Isfahan

Province

Isfehan

Postal code

8451731167

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.IAU.FALA.REC.1398.49

Health conditions studied

1

Description of health condition studied

Congestive heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description
Heart function
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Echocardiogram

2

Description
Lipid profile
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Auto analyzer biochemistry

3

Description
Total antioxidant capacity
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Assay kit, Spectrophotometer

4

Description
Paraoxonase enzyme activity assay
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Assay kit, Spectrophotometer

5

Description
Arylesterase enzyme activity assay
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Assay kit, Spectrophotometer

6

Description
LDL separation from plasma
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Ultracentrifuge

7

Description
Assessment of LDL oxidation
Timepoint
Before of intervention, 60 days after of intervention
Method of measurement
Cuso4, Spectrophotometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Lycopene, one 25 mg tablet daily, for 60 days, 21st Century company, made in USA, contains 25 mg of lycopene and 170 mg of calcium carbonate
Category
Treatment - Drugs

2

Description
Control group: Placebo, One tablet daily for 60 days,
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran hospital
Full name of responsible person
Laila Rejali
Street address
after Shahristan Bridge, Mushtaq third St., Bozormehr Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Owner
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Laila Rejali
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document

Some of the data related to the main outcome will be shared.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Optimization of this study to help patients

From where data/document is obtainable

Laila Rejali: lailarejali@yahoo.com Dr.Hashem Nayeri: hnaieri@gmail.com

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

Official letter to Leila Rejali and Dr. Hashem Nayeri

Comments