

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluating the effect of lycopene on cardiac biomarkers, Inflammatory factors and Matrix metalloproteinase 9 in patients undering elective Percutaneous Coronary Intervention

Protocol summary

Study aim

Investigation of the effects of lycopene on serum levels of cardiac biomarkers of myocardial ischemia and high-sensitivity C-reactive protein (hs-CRP) in patients undergoing elective coronary intervention (PCI)

Design

Two arm parallel group randomized controlled clinical trial

Settings and conduct

Chamran Hospital, Cardiovascular Research Center

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Over 40 years old 2. Use of aspirin 80 to 100 mg daily for at least 5 days before PCI 3. Completion of informed consent 4. Being a candidate for elective PCI 5. No use of other antioxidants including vitamins C and E, coenzyme Q10, selenium, anthocyanin supplements and lycopene supplements 1 week before study 6. No use of fish oil and omega-3 from 1 week before the study Exclusion criteria: 1. Uncontrolled hypertension 2. Thrombocytopenia 3. Renal dysfunction (creatinine clearance less than 30 ml / min). 4. Hepatic dysfunction (liver enzymes more than three times the upper limit of normal) 5. Active bleeding 6. Pregnancy 7. Allergy to lycopene

Intervention groups

Control group: PCI with standard treatment (aspirin, statin, and beta-blocker) Experimental group: PCI with standard treatment (aspirin, statin, and beta-blocker) with lycopene 30 mg 12 hours before PCI and 15 mg just after and 8 hours after PCI

Main outcome variables

Serum levels of Troponin I, CK-MB, hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191018045149N1**

Registration date: **2020-04-07, 1399/01/19**

Registration timing: **retrospective**

Last update: **2020-04-07, 1399/01/19**

Update count: **0**

Registration date

2020-04-07, 1399/01/19

Registrant information

Name

Sedigheh Asgary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3611 5310

Email address

sedighehasgary@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

2017-12-21, 1396/09/30

Actual recruitment end date

2018-08-22, 1397/05/31

Trial completion date

2018-08-22, 1397/05/31

Scientific title

Evaluating the effect of lycopene on cardiac biomarkers, Inflammatory factors and Matrix metalloproteinase 9 in

patients undergoing elective Percutaneous Coronary Intervention

Public title

The effect of lycopene on serum level of cardiac biomarkers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient undergoing elective PCI surgery over 40 years old. Consumption of 80 to 100 mg aspirin daily for at least 5 days before PCI Completion of informed consent No Consumption of other antioxidants including vitamins C and E, coenzyme Q10, selenium, anthocyanin supplements and lycopene supplements 1 week before study No use of fish oil and omega-3 by 1 week before study

Exclusion criteria:

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was used for patients' allocation to the groups. For this, an online random number generator was used (available at: <https://www.random.org/sequences>) so that even and odd numbers were considered for drug and control groups, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar girib street

City

Esfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2017-11-26, 1396/09/05

Ethics committee reference number

IR.MUI.REC.1396.3.574

Health conditions studied

1

Description of health condition studied

Patients undergoing elective coronary intervention (PCI) treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum levels of CK-MB, Troponin I and hs-CRP were measured in patients

Timepoint

Blood samples from both groups 12 hours before the intervention, 8 and 12 hours one and six months after the intervention

Method of measurement

5 ml blood was taken from the patient to measure serum CK-MB, Troponin I and hs-CRP levels.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: PCI with standard treatment (aspirin, statin, and beta-blocker)

Category

Treatment - Devices

2

Description

Experimental group: PCI with standard treatment (aspirin, statin, and beta-blocker) with lycopene 30 mg 12 hours before PCI and 15 mg just after and 8 hours after PCI

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital, Cardiovascular Research Center

Full name of responsible person

Dr. Rasoul Soltani

Street address

Hezar girib street

City

Esfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Rasoul Soltani

Street address

Hezar jirib street

City

Esfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3792 7067

Email

soltani@pharm.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

Dr. Rasoul Soltani

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Hezar jirib

City

Esfahan

Province

Isfahan

Postal code

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Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

confidentiality of patients' data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available