Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of lycopene on cardic 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)

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+98 31 3611 5310

Email address
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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 cardic biomarkers, Inflammatory factors and Matrix metalloproteinase 9 in

patients undering 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
Isfehan
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
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Hezar girib street
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Sponsors / Funding sources

1

Sponsor

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Esfahan University of Medical Sciences
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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
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Person responsible for updating data

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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