Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of effects of combined of supplement with carnitine and coenzyme Q10, versus therapeutic lifestyle changes (TLC Diet) diet on cardiovascular risk factors, function and quality of life after angioplasty in patients with experience of myocardial infarction

Protocol summary

Summary

The aim of this study is to evaluate of combined of supplement with carnitine and coenzyme Q10, versus therapeutic lifestyle changes (TLC Diet) diet on cardiovascular risk factors, function and quality of life after angioplasty in patient with experience of myocardial infarction. This is a 2 x 2 factorial design clinical trial with Sample size 128 that with simple randomization divided into 4 groups. Every group has 32 precipitant. The first group only will receive therapeutic Lifestyle Changes (TLC) diet and second group will receive only the supplement L-carnitin and coenzyme Q10 and third group will receive two supplement L-carnitin and coenzyme Q10 and therapeutic Lifestyle Changes diet then fourth group is control group that will receive usual care. For the first and second group, plus education a therapeutic lifestyle change diet is formulated based on individual patient characteristics. Patient in the second and third group, dietary supplement carnitine 1200 mg and co-enzyme Q10 150 mg will receive. This study is a single blind and investigator is aware of the type of intervention. Patients with a first myocardial infarction, primary angioplasty, and hyperlipidemia (LDL >130) are selected for intervention If the patient has history of warfarin consumption or angioplasty complication exclude in survey. Duration of intervention is 3 month. Before and after the intervention will measure inflammatory marker (CRP and IL 6) lipid profile (LDL, HDL, and TG), ejection fraction, physical activity and quality of life.

General information

Acronym

Therapeutic Lifestyle Changes Diet (TLC)

IRCT registration information

IRCT registration number: **IRCT2282620150719N1**
Registration date: **2015-07-19, 1394/04/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-19, 1394/04/28

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences, School of Nutrition and Food Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

government source ,Shiraz University of Medical Sciences

Expected recruitment start date

2015-05-09, 1394/02/19

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of effects of combined of supplement with carnitine and coenzyme Q10, versus therapeutic lifestyle changes (TLC Diet) diet on cardiovascular risk factors, function and quality of life after angioplasty in patients with experience of myocardial infarction

Public title
Effect of combined of supplement with carnitine and coenzyme Q10, versus therapeutic lifestyle changes (TLC Diet) diet on myocardial infarction patients.
Purpose
Supportive
Inclusion/Exclusion criteria
inclusion criteria: first experience of myocardial infarction; age between 40 -65; candidate for angioplasty revascularization; LDL >130؛ without anti lowering lipid six month ago; ejection fraction between 30-60; receive atorvastatin 80 mg daily; exclusion criteria: allergy with atorvastatin; history of cardiac event after angioplasty; patient with arrhythmia or congestive heart failure; history of consumption of antioxidant such as vitamin C, E and omega 3; history of consumption warfarin; history of documented psychological disease ; leave the patient before 60 days after intervention in RCT;
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz UniversityMedical Sciences
Street address
Zand Blov,Shiraz University Medical Sciences
City
Shiraz
Postal code
713451978
Approval date
2015-04-19, 1394/01/30
Ethics committee reference number
IR.SUMS.REC.1394.1

Health conditions studied

1

Description of health condition studied
myocardial infarction
ICD-10 code
I21
ICD-10 code description
Acute myocardial infarction

Primary outcomes

1

Description
LDL
Timepoint
24 hours after myocardial infarction than 3 month after intervention
Method of measurement
enzymatic method calculate

Secondary outcomes

1

Description
quality of life
Timepoint
10 days after myocardiad in farction
Method of measurement
MacNew questionaire

2

Description
ejection fraction
Timepoint
24 houre after myocardiad in farction
Method of measurement
echocardiography by specilalist

3

Description
Triglyceride (TG)
Timepoint
24 houre after myocardiad in farction and 3 mouth after intervention
Method of measurement
Photometric method

4

Description
High-density lipoprotein (HDL)
Timepoint
24 houre after myocardiad in farction and 3 mouth after intervention
Method of measurement
Photometric method

5

Description
Physical Activity
Timepoint
7 days before myocardial infarction then 3 month after intervention
Method of measurement
Intinternational Physical Activity Questionnaire - Short Form (IPAQ-SF)

6

Description
H- CRP
Timepoint
24 houre after myocardiad in farction and 3 mouth after intervention
Method of measurement
ELISA by micropipette reader

7

Description
IL-6
Timepoint
24 houre after myocardiad in farction and 3 mouth after intervention
Method of measurement
ELISA

Intervention groups

1

Description
control group: without any intervention, patient receive routine care
Category
Other

2

Description
Diet and supplement group: patient receive therapeutic life style change diet and two supplement , l-carnitin with dose 1200 mg , co- Q10 with dose 150 mg
Category
Treatment - Other

3

Description
Diet group: patient receive therapeutic life style change diet suitable with weight and individual properties
Category
Lifestyle

4

Description
supplement group: patient receive two supplement , l-carnitin with dose 1200 mg , co- Q10 with dose 150 mg
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra Heart Hospital in Shiraz
Full name of responsible person
Hojat Allah Roosta
Street address
Blov.Siboiehe
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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hashemi Seid Basir Dr
Street address
Zand Blvd,Shiraz University of Medical Sciences
City
Shiraz
Grant name
معاونت پژوهشی
Grant code / Reference number
Vice chancellery for research affair
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Hassan Eftekhari

Position
PHD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty