

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Mohammad Hossein Sharifi

Name of organization / entity

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

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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 University Medical 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 myocardial infarction

Method of measurement

MacNew questionnaire

2

Description

ejection fraction

Timepoint

24 hours after myocardial infarction

Method of measurement

echocardiography by specialist

3

Description

Triglyceride (TG)

Timepoint

24 hours after myocardial infarction and 3 month after intervention

Method of measurement

Photometric method

4

Description

High-density lipoprotein (HDL)

Timepoint

24 hours after myocardial infarction and 3 months after intervention

Method of measurement

Photometric method

5

Description

Physical Activity

Timepoint

7 days before myocardial infarction then 3 months after intervention

Method of measurement

International Physical Activity Questionnaire - Short Form (IPAQ-SF)

6

Description

H- CRP

Timepoint

24 hours after myocardial infarction and 3 months after intervention

Method of measurement

ELISA by micropipette reader

7

Description

IL-6

Timepoint

24 hours after myocardial infarction and 3 months 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

Bldv.Siboehe

City

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

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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