

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of L-Carnitin on IL6 and HS- CRP levels after Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim

Effect of L-Carnitin on IL6 and HS- CRP levels after Coronary Artery Bypass Graft Surgery

Design

Clinical trials with community based and pragmatic control group, with parallel groups ,randomized

Settings and conduct

The present study will be designed as a randomized clinical trial. All patients with inclusion criteria will be enrolled in the study after completing a written explanation and obtaining written consent and will enter the treatment groups using a random number table.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-70 years; Complete the consent form Not receiving non-steroid anti-inflammatory drugs for at least 2 weeks before surgery ; Not receiving corticosteroid; Exclusion criteria: Drinking alcohol and drugs; History of seizure or epilepsy; Patients with a history of cerebrovascular diseases ; Chronic liver failure (enzymes higher than 2 times normal); Chronic renal failure (STAGE 4 & 5); Coronary artery bypass surgery without using a bypass pump; Emergency surgery; CABG surgery with other simultaneous actions; EF<40%

Intervention groups

The first treatment group (20 people), with standard interactions and treatments, receive 1 g l-carnitine per liter of Cardioplegia solution. The second group treatment (20 people) received standard 3-grams of L-carnitine per liter of Cardioplegia solution. Patients in the control group (20 people) also receive normal saline in addition to standard treatment (this group does not receive any treatment other than standard treatment).

Main outcome variables

IL6 and HS- CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150725023332N1**

Registration date: **2019-09-23, 1398/07/01**

Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**

Update count: **0**

Registration date

2019-09-23, 1398/07/01

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2283 1058

Email address

alirezajahangiri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-Carnitin on IL6 and HS- CRP levels after Coronary Artery Bypass Graft Surgery

Public title

Effect of L-Carnitin on Coronary Artery Bypass Graft

Surgery

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with mild-to-moderate heart failure (EF = 55-40%) for coronary artery bypass graft surgery (elective CABG)
Exclusion criteria:
 History of seizure or epilepsy Patients with a history of cerebrovascular diseases Chronic liver failure (enzymes higher than 2 times normal) Chronic renal failure (STAGE 4 & 5) Drinking alcohol and drugs Coronary artery bypass surgery without using a bypass pump CABG surgery EF<40%

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this clinical trial, the randomization process was performed simply (By creating tables of numbers and coding patients based on numbers in the table) .The subjects were randomly divided into three separate blocks.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Biomedical Research of Shahid Beheshti University

Street address

Next to Ayatollah Taleghani Hospital ,Evin , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

198396-3113

Approval date

2018-04-15, 1397/01/26

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.432

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Graft Surgery

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description

Serum HS-CRP and IL-6 levels in three groups of patients

Timepoint

At baseline and 24 hours after surgery

Method of measurement

Blood sampling, blood serum isolation, and finally biochemical tests

Secondary outcomes

1

Description

Measurement of serum levels of CPK-MB and Troponin in patients undergoing surgery

Timepoint

It will be measured at baseline 8 and 24 hours after surgery

Method of measurement

Blood sampling, blood serum isolation, and finally biochemical tests

Intervention groups

1

Description

Intervention group: Patients in the first group (20 patients) with standard interactions and treatments receive 1 g l-carnitine per liter of Cardioplegia solution.

Category

Treatment - Surgery

2

Description

Intervention group: The second group therapy (20 people), in addition to standard treatments, receives 3 g

of l-carnitine per liter of Cardioplegia solution.

Category

Treatment - Surgery

3**Description**

Control group: For patients in the control group (20 people), they receive normal saline in addition to standard treatment (this group does not receive any treatment except standard treatment).

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Masih Daneshvari Hospital

Full name of responsible person

Alireza Jahangirifard

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

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Taleghani Hospital, Shahid Beheshti University of Medical Sciences and Health Services

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza jahangirifard

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable