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Does the supplement L-carnitine have an effect on cell recovery after coronary artery bypass grafting?

Submission date 06/11/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[ ] Protocol
Registration date 26/11/2019	**Overall study status** Completed	[ ] Statistical analysis plan
		[ ] Results
Last Edited 27/04/2020	**Condition category** Circulatory System	[ ] Individual participant data
		[ ] Record updated in last year

Plain English summary of protocol

Background and study aim
Coronary artery bypass grafting (CABG) surgery is one of the most common cardiac surgeries worldwide. Patients undergoing surgery because of the possibility of advanced atherosclerosis, mild systemic inflammation, and other comorbidities are always classified in high-risk groups. For this reason, predictive markers are essential for risk assessment. The Absolute Neutrophil to Lymphocyte Ratio (NLR) and Absolute Platelet to Lymphocyte Ratio (PLR) have been a topic of great interest in recent years in the field of heart disease and its low cost and availability properly noted.
L-carnitine is mainly made in the liver and kidney. L-carnitine is a key component of the transport of activated fatty acids through the mitochondrial membrane and has been shown in recent studies to have antioxidant and anti-inflammatory effects. It is mainly (approximately 98%) found in muscle tissue. The amount in the heart muscle is more than three times that of the striated muscle. In some heart diseases, L-carnitine deficiency has been observed. Studies have also evaluated the efficacy of L-carnitine supplementation orally or intravenously before, during, and after CABG.
In this study, we will investigate the effect of pre-operative L-carnitine supplementation on Neutrophil to Lymphocyte Ratio (NLR) and Platelet to Lymphocyte Ratio (PLR).

Who can participate?
Adults undergoing elective CABG

What does the study involve?
Participants are randomly allocated to one of three groups.
Those in the first group receive 2gr L-carnitine 12 hours before surgery.
The second group will receive 5gr L-carnitine 12 hours before surgery.
The third group will receive a placebo.
All groups will have standard CABG surgery.

What are the possible benefits and risks of participating?
Those in the L-carnitine group might benefit from its anti-inflammatory effect.

Where is the study run from?
Cardiovascular research center, Shahid Beheshti University of Medical Sciences, Shahid Modarres Hospital, Tehran, (Iran)

When is the study starting and how long is it expected to run for?
November 2019 to March 2020

Who is funding the study?
Deputy of Research of Shahid Beheshti School of Medicine

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IR.SBMU.RETECH.REC.1397.432

Study information

Scientific Title
The effect of L-carnitine on neutrophil-lymphocyte ratio and platelet-lymphocytes ratio in patients undergoing coronary artery bypass grafting

Study objectives
Regarding L-carnitine effect as an anti-inflammatory agent, administration of this supplement before coronary artery bypass grafting (CABG) can impact neutrophil-lymphocyte ratio and platelet-lymphocytes ratio

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2018, Ethics committee of Shahid Beheshti Medical University (Arabi Ave., Tehran, 193954719, Iran; +9822439951; mpd@sbmu.ac.ir), ref: IR.SBMU.RETECH.REC.1397.60

Study design
Interventional single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiac surgery

Interventions
Participants undergoing CABG are divided into three groups which receive a dose of supplement /placebo 12 hours before surgery:
1. Administration of 2 gr l-carnitine
2. Administration of 5 gr l-carnitine
3. Administration of placebo

Complete blood count (CBC) differential blood tests will be performed to analyse neutrophil-lymphocyte ratio and platelet-lymphocytes ratio before the surgery and each of 3 postoperative days.

Intervention Type
Supplement

Primary outcome measure
Measured by CBC differential blood test pre-operatively and daily for three days post-surgery:
1. Neutrophil-Lymphocyte ratio
2. Platelet-Lymphocytes ratio

Secondary outcome measures
Pre-operatively and daily for three days post-surgery:
1. Echocardiographic indexes measured using ECG
2. The changes of mean platelet volume measured by CBC differential blood test
3. The changes of red cell distribution width measured by CBC differential blood test

Overall study start date
23/11/2019

Completion date
19/03/2020

Eligibility

Key inclusion criteria
1. Patients undergoing elective on-pump CABG for the first time
2. Adult aged 18 - 80 years
3. No history of NSAIDs and or corticosteroids use for four weeks before the operation
4. No history of inflammatory disorder for six months before the operation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Renal failure or creatinine level >1.5 mg/d
2. Hepatic failure
3. Inability to swallow oral medications
4. Contraindication to L-carnitine therapy
5. Emergent CABG
6. Use of L-carnitine within 4 weeks before the start of the study

7. Major surgery less than 28 days before the start of treatment
8. Recent history of any cancer
9. Prior radiotherapy or chemotherapy less than 4 weeks prior
10. Moderate to severe left ventricular dysfunction (EF<40)
11. Re-operation

Date of first enrolment
07/12/2019

Date of final enrolment
20/02/2020

Locations

Countries of recruitment
Iran

Study participating centre
Shahid Modarres Hospital
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Sponsor information

Organisation
Shahid Beheshti University of Medical Sciences

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Sponsor type
University/education

ROR

https://ror.org/034m2b326

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
20/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request