# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of L-Carnitine on QT-Dispersion of patients with acute myocardial infarction in Rafsanjan Ali Ibn-Abitaleb Hospital: A randomized, double-blind, placebo-controlled trial

## Protocol summary

**Study aim**

Investigate the antioxidant effects of L-carnitine on QT-dispersion of patients with acute myocardial infarction hospitalized in Ali Ibn Abi Talib Hospital in Rafsanjan so that, if possible, the effect of this biological substance, even if possible these patients have a poor prognosis.

**Design**

Clinical trial with control group, double blind, randomized.

**Settings and conduct**

The ECG is taken from the patient on the first day and at the end of the 8th week, and QT-dispersion is calculated Oral L-carnitine tablets at a dose of 250 mg will be administered twice daily for 8 weeks. Population: Patients admitted to CCU of Ali Ibn Abi Talib Hospital in Rafsanjan. In this study, the patient and the investigator were not informed about the type and method of administration of the drug in order to observe the details of the stud

**Participants/Inclusion and exclusion criteria**

Participants/Inclusion: Patients with Acute Myocardial Infarction Patients undergoing angiography have more than 80% coronary stenosis,The type and extent of MI and age restriction are not relevant in this study. Participants/ exclusion: Moderate and severe valvular disease, Pregnancy, Left and right bundle branch block, Patients taking vitamin supplements, Patients taking QT prolonging drugs Underlying diseases such as diabetes and liver failure and chronic renal failure grade 4 and 5.

**Intervention groups**

Intervention group: 60 patients with diagnosis of acute myocardial infarction (oral L-carnitine tablet at a dose of 250 mg twice daily for 8 weeks). Control group: 60 patients with acute myocardial infarction (Placebo (starch tablets) are powdered in the same shells and will be prescribed twice daily for 8 weeks).

**Main outcome variables**

QT Distribution; Vascular Stenosis Percentage; hypertension

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190128042525N3**
Registration date: **2020-06-10, 1399/03/21**
Registration timing: **retrospective**

Last update: **2020-06-10, 1399/03/21**
Update count: **0**

**Registration date**

2020-06-10, 1399/03/21

**Registrant information**

**Name**

Gholamreza Bazmandegan

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 34 3428 0185

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-10-23, 1397/08/01

**Expected recruitment end date**

2019-06-22, 1398/04/01

**Actual recruitment start date**

2018-10-23, 1397/08/01

**Actual recruitment end date**

2019-08-23, 1398/06/01

**Trial completion date**

2019-08-23, 1398/06/01

**Scientific title**

Effect of L-Carnitine on QT-Dispersion of patients with acute myocardial infarction in Rafsanjan Ali Ibn-Abitaleb Hospital: A randomized, double-blind, placebo-controlled trial

**Public title**

Effect of L-Carnitine on QT-Dispersion of patients with acute myocardial infarction in Rafsanjan Ali Ibn-Abitaleb Hospital: A randomized, double-blind, placebo-controlled trial

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with Acute Myocardial Infarction with History, Examination, ECG and Cardiac Enzymes and Angiography Patients undergoing angiography have more than 80% coronary stenosis The type and extent of MI and age restriction are not relevant in this study.

**Exclusion criteria:**

Moderate and severe valvular disease Pregnancy Left and right bundle branch block Patients taking vitamin supplements Patients taking QT prolonging drugs (amiodarone, sotalol, quinidine, azithromycin, clarithromycin, erythromycin) Underlying diseases such as diabetes (due to the effect of diabetes-induced oxidative stress on the antioxidant effects of L-carnitine) and liver failure (due to hepatic drug metabolism), and chronic renal failure grade 4 and 5 (GFR <30 mL / min / 1.73)

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **200**

Actual sample size reached: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization: simple randomization Unit of randomization: individual Tools used in randomization: table of random numbers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double blind randomized clinical trial. In this study, in order to observe the details of the double-blind study, the patient and the investigator are not informed of any type and method of administration, only the physician is aware of the type and method of administration of the drug and placebo, and how the study and control groups are divided.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of rafsanjan University of Medical Sciences

**Street address**

Ali Ibn Abital Square

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717937555

**Approval date**

2018-08-08, 1397/05/17

**Ethics committee reference number**

IR.RUMS.REC.1397.096

## Health conditions studied

### 1

**Description of health condition studied**

Patients with acute myocardial infarction

**ICD-10 code**

I21

**ICD-10 code description**

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

## Primary outcomes

### 1

**Description**

In the study "Effect of oral L-carnitine tablets on QT-dispersion in patients with acute myocardial infarction hospitalized at Ali Ibn Abi Talib Hospital in Rafsanjan" the primary outcome could be "reduced QT-dispersion".

**Timepoint**

In the study "Effect of oral L-carnitine tablets on QT-dispersion in patients with acute myocardial infarction hospitalized in Hazrat Ali Ibn Abi Talib Hospital in Rafsanjan" is the timing of measurement of QT-dispersion in the first day of study and last day.

**Method of measurement**

The Method of measurement: how to measure the

outcome variable: QT-dispersion is calculated by measuring the difference between the largest and the smallest QT. Interval in 12-lead of Electrocardiogram.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group:60 patients with acute myocardial infarction admitted to Ali Ibn Abi Talib Hospital in Rafsanjan. L-carnitine treatment group. (Oral L-carnitine tablets will be prescribed twice daily for up to 24 hours from hospitalization at a dose of 250 mg daily for 8 weeks).
**Category**
Prevention

### 2

**Description**
Control group: 60 patients with acute myocardial infarction admitted to Ali Ibn Abi Talib Hospital in Rafsanjan. Placebo (starch tablets) are milled and powdered in the same shells and are reheated twice daily for 8 weeks.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ali Ibn Abi Talib Hospital in Rafsanjan
**Full name of responsible person**
Fateme Askari Hosni
**Street address**
Ali Ibn Abitaleb Square
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Rafsanjan University of Medical Sciences
**Full name of responsible person**
Gholamreza Bazmandegan
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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**
Rafsanjan University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Private
**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**
Rafsanjan University of Medical Sciences
**Full name of responsible person**
Fateme Askari Hosni
**Position**
General physician
**Latest degree**
Medical doctor
**Other areas of specialty/work**
General Practitioner
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be 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