

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Assessment of effect of L-Carnitine supplement on subclinical LV systolic dysfunction detected by speckletracking echocardiography in patients with ESRD under hemodialysis

Protocol summary

Study aim

Determination of effect of L-Carnitine supplement on subclinical LV systolic dysfunction detected by Speckle Tracking echocardiography in patients with ESRD under hemodialysis

Design

In this study at first Hemodialysis patient undergo speckle tracking echocardiography and their LVEF data will record then they treat with L-Carnitine supplement for 3 months after each session of HD and then again undergo Speckle echo and data will record and analysis will be done. this study will done on 34 hemodialysis patient and has no control groups

Settings and conduct

This study will execute in the Namazi hospital Echocardiography Lab and patient will randomized select from Namazi hospital hemodialysis ward

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Left ventricular ejection fraction more than or equal of 50 percent 2) 3 times a week routine and regular hemodialysis 3) Agreement to take part in the study 4) Hemodialysis patient with age more than 18 who start hemodialysis for more than 3 months 5) If the patient have been used L-Carnitine supplement before the study, should stop using it for at least 1 week for entrance to our study
Exclusion criteria: 1) Patient who used medicine which make drug interactions with the supplement 2) Patients who are pregnant or have Liver Failure, Thyroid dysfunction, Nephrotic syndrome, Cancers, Vasculitis or other inflammatory disease 3) Disagreement to take part in the study

Intervention groups

Intervention fulfill in the hemodialysis patient. The randomized selected patient will undergo echocardiography and then treat with L-Carnitine after each session of hemodialysis and after three months echo will done for the result

Main outcome variables

Left ventricular ejection fraction and longitudinal global strain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221128056646N1**

Registration date: **2022-12-18, 1401/09/27**

Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**

Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name

Mina Keshtkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3629 0110

Email address

minakeshtkar_828@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effect of L-Carnitine supplement on subclinical LV systolic dysfunction detected by speckletracking echocardiography in patients with ESRD under hemodialysis

Public title

Assessment of effect of L-Carnitine supplement on subclinical LV systolic dysfunction detected by speckletracking echocardiography in patients with ESRD under hemodialysis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Left ventricular ejection fraction more than or equal of 50 percent 3 times a week routine and regular hemodialysis Agreement to take part in the study Hemodialysis patient with age more than 18 who start hemodialysis for more than 3 months If the patient have been used L-Carnitine supplement before the study, should stop using it for at least 1 week for entrance to our study

Exclusion criteria:

Patient who used medicine which make drug interactions with the supplement Patients who are pregnant or have Liver Failure , Thyroid dysfunction, Nephrotic syndrome, Cancers, Vasculitis or other inflammatory disease Disagreement to take part in the study

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

No 7, second floor, Daneshvaran st, Shahid Mokhtari st, Chamran Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

7194896847

Approval date

2022-09-20, 1401/06/29

Ethics committee reference number

IR.SUMS.MED.REC.1401.321

Health conditions studied**1****Description of health condition studied**

Patients with ESRD under hemodialysis

ICD-10 code**ICD-10 code description**

speckle echo

Primary outcomes**1****Description**

Ejection fraction is defined with the ability of left ventricle to pump blood in each heart beat and bring up with percent

Timepoint

Ejection fraction measure in the beginning of study and the after 3 months of receiving L-Carnitine supplements

Method of measurement

Speckle tracking echocardiography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: we do this study with L-Carnitine oral solution with dosage of 1000 mg right after each session of hemodialysis which prescribe for 3 months. The manufacturer company is Bonyan Salamat Kasra

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Mina keshtkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mina Keshtkar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more data

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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