Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

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 hemodiylisis

Design
In this study at first Hemodialysis pateint undergo speckle tracking echocardiogarphy 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 hemodylisis pateint and has no control groups

Settings and conduct
This study will execute in the Namazi hospital Echocardiography Lab and pateint will randomized slect from Namazi hospital hemodialysis ward

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1)Left ventricular ejection fraction more than or equal of 50 persent 2)3 times a weak 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 pateint have been used L-Carnetine supplement before the study,should stop using it for at least 1 weak for entrance to our study Exclusion criteria: 1)Pateint who used medicine which make drug intractions with the supplement 2)Pateints who are pregnant or have Liver Failure , Thyroid dysfunction, Nephrotic syndrome,Cancers, Vasculitis or other inflamatory disease 3)Disagreement to take part in the study

Intervention groups
intervention fulfil in the hamodialysis patient.the randomiz selected pateint will undergo echocardiogarphy and then treat with L-Carnitin after each session of hemodialysis andafter three months echo will done for the result

Main outcome variables
Left venticular 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
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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 hemodiylisis

Public title
Assessment of effect of L-Carnitine supplement on subclinical LV systolic dysfunction detected by speckletracking echocardiography in patients with ESRD under hemodiylisis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Left ventricular ejection fraction more than or equal of 50 persent 3 times a weak 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 pateint have been used L-Carnetine supplement before the study,should stop using it for at least 1 weak for entrance to our study
Exclusion criteria:
Pateint who used medicine which make drug intractions with the supplement Pateints who are pregnant or have Liver Failure , Thyroid dysfunction, Nephrotic syndrome,Cancers, Vasculitis or other inflamatory 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 hemodiylisis
ICD-10 code
ICD-10 code description
speckle echo

Primary outcomes

1

Description
Ejection fraction is define with the ability of left venticle to pump blood in each haert beat and bring up with percent
Timepoint
Ejection fraction measure in the begining of study and the after 3months of recivining 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 manufactor 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
Street address
No 7,second floor,Daneshvaran st, Shahid Mokhtari st, Chamran Blvd,Shiraz
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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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7134814336
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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

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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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