Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of oral l-carnitine on echocardiography criteria in patients with pulmonary artery hypertension due to dialysis

Protocol summary

Study aim
Determining the effectiveness of oral L-carnitine on echocardiographic parameters of patients with pulmonary artery hypertension in dialysis patients

Design
A double-blind clinical trial with a control group and randomized using a random number table will be conducted on 40 dialysis patients.

Settings and conduct
This double-blind clinical trial study will be conducted in 40 dialysis patients undergoing hemodialysis treatment in Shahrekord dialysis centers. Group 1: patients with routine treatment + L-carnitine 1000 mg every 12 hours for 3 months Group 2: patients with routine treatment + placebo for 3 months.

Participants/Inclusion and exclusion criteria
Entry criteria: age over 13 years, experience of at least six months of hemodialysis, having a case in the dialysis department of the desired center, performing dialysis 2 or 3 times a week for 3-4 hours each time, not having a physical or mental disability, maintaining a stable dry weight Patient . Exit criteria: Suffering from chronic physical disorders such as heart, respiratory, and liver diseases, kidney transplant history, unwillingness to continue cooperation, death, travel, occurrence of unwanted drug side effects, not taking medicine for more than a week

Intervention groups
Intervention: routine treatment + L-carnitine 1000 mg every 12 hours for 3 months Control: routine treatment + placebo

Main outcome variables
Decrease in pulmonary artery pressure Improving the function of the right ventricle, improving the SPO2 level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230425057989N1**
Registration date: **2023-05-07, 1402/02/17**
Registration timing: **prospective**

Last update: **2023-05-07, 1402/02/17**
Update count: **0**

Registration date
2023-05-07, 1402/02/17

Registrant information

Name
Afiyeh Mirzaali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3236 2238

Email address
afiyeh.mirzaali@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-09, 1402/02/19

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of oral l-carnitine on echocardiography criteria in patients with pulmonary artery hypertension due to dialysis

Public title
Effect of oral L-carnitine on echocardiography of dialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
More than 13 years of age History of at least six months of hemodialysis Having a case in the dialysis department Performing dialysis 2 or 3 times a week for 3-4 hours each time Not having physical and mental disabilities The patient's dry weight remains constant
Exclusion criteria:
Suffering from chronic physical disorders such as heart, respiratory, and liver diseases Kidney transplant history Unwillingness to continue cooperation Death Travel Occurrence of unwanted drug side effects Not taking medicine for more than a week
Age
From **13 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
To create a random sample, a simple randomization method using a table of random numbers will be used. In this method, the information of all dialysis patients of the studied dialysis centers is collected and their names are written in a list and each patient will be assigned a number in the order of writing. Then, using the table of random numbers (choosing the first number randomly, moving from left side to right in the table of random numbers and considering the last two digits of each random number) according to the sample size, the patients who will enter the study are selected. To determine the patient placement group (intervention or control) according to the selection order of the people who entered the study, the people whose selection order is odd number will be placed in the intervention group and other people will be in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The type of blinding of the study is double-blind, and the patients and the statistical consultant are unaware of the type of treatment. Given that the packaging of the placebo pill is completely similar to the original drug, and the researcher and the patient are not aware of the contents of the package. And the labeling is done with a random code.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Kashani street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8813833435
Approval date
2021-10-18, 1400/07/26
Ethics committee reference number
IR.SKUMS.REC.1400.157

Health conditions studied

1

Description of health condition studied
pulmonary hypertension
ICD-10 code
I27.2
ICD-10 code description
Other secondary pulmonary hypertension

Primary outcomes

1

Description
Pulmonary artery pressure
Timepoint
Before and after 3 months from the start of the intervention
Method of measurement
Echocardiography

2

Description
Arterial oxygen saturation
Timepoint
Before and after 3 months from the start of the intervention
Method of measurement

Pulse oximetry

Secondary outcomes

1

Description
Number of times of hemodialysis per week
Timepoint
Before and after 3 months from the start of the intervention
Method of measurement
Number of times of hemodialysis per week

2

Description
Right ventricular function
Timepoint
Before and after 3 months from the start of the intervention
Method of measurement
Echocardiography

3

Description
Shortness of breath
Timepoint
Before and after 3 months from the start of the intervention
Method of measurement
NYHA (New York Heart Association Functional Classification)

Intervention groups

1

Description
Intervention group: First, echocardiography, 6-minute walk test (6MWT) and NYHA criteria are examined for patients. The results of 6MWT distance, pulse count and distance covered during 6 minutes and SpO2 with pulse oximetry will be measured at the end, one minute and 3 minutes after the completion of the 6MWT test. In NYHA criteria, patients are scored according to their statements during the medical interview or visible symptoms. In addition to routine treatment, patients receive L-carnitine 1000 mg every 12 hours for three months. Finally, after 3 months of receiving the drug, echocardiography, NYHA criteria and 6MWT will be repeated and data will be collected.
Category
Treatment - Drugs

2

Description
Control group: First, echocardiography, 6-minute walk test (6MWT) and NYHA criteria are examined for patients. The results of 6MWT distance, pulse count and distance covered during 6 minutes and SpO2 with pulse oximetry will be measured at the end, one minute and 3 minutes after the completion of the 6MWT test. In NYHA criteria, patients are scored according to their statements during the medical interview or visible symptoms. In addition to routine treatment, patients receive placebo every 12 hours for three months. Finally, after 3 months of receiving the placebo, echocardiography, NYHA criteria and 6MWT will be repeated and data will be collected.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis centers in Shahrekord city (Dialysis Departments of Hajar Hospital, Dialysis Department of
Full name of responsible person
Zahra Hbibi
Street address
Kashani street
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8816754633
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dr_z_habibi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
Street address
Kashani Street
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Sharekord
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Email
afiyeh.mirzaali@gamil.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Afiyeh Mirzaali
Position
Medical Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Zahra Habibi
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assistant professor
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Subspecialist
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Person responsible for updating data

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Medical Assistant
Latest degree
Medical doctor
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Internal Medicine
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afiyeh.mirzaali@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
If there are conditions, all our data will be shared except personal information of people. The use of our data will

only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address afiyeh.mirzaali@gmail.com or the contact number 0098911793259

What processes are involved for a request to access data/document

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments