

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

afiye.h.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 Hbib

Street address

Kashani street

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Chahar-Mahal-va-Bakhtiari

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8816754633

Phone

+98 38 3222 0016

Email

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

City

Sharekord

Province

Chahar-Mahal-va-Bakhtiari

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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

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**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Zahra Habibi

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Afiyeh Mirzaali

Position

Medical Assistant

Latest degree

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Email

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