

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of midodrine with L -carnitine in the treatment of intradialytic hypotension

Protocol summary

Study aim

Comparison of midodrine with L -carnitine in the treatment of intradialytic hypotension

Design

Clinical trial with control group, with parallel group, single blind, randomized, on 30 patients. For randomization, block randomization are used. In order to blind the patients, they do not communicate with each other and do not know which group they belong to.

Settings and conduct

Dialysis patients of Namazi and Shahid Faqihi Hospitals, who have been on dialysis for at least two months and who undergo dialysis at least twice a week, and who have a drop in blood pressure during dialysis in more than 50% of the dialysis sessions according to the variable definition of the plan, were selected and then randomized into two groups of 15 people. One group of patients was given oral L-carnitine at a dose of 1000 mg before each dialysis session and the second group was given 5 mg midodrine half an hour before each dialysis for one month. At the end, the effect of the drug in two different groups on blood pressure drop during dialysis is investigated. To blind the patients, they are not in contact with each other and do not know which group they belong to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Dialysis patients of Namazi and Shahid Faqihi hospitals - At least two months have passed since they started dialysis - Dialysis at least twice a week - In more than 50% of dialysis sessions, intradialytic hypotension according to the variable definition of the plan. Exit criteria: Intradialytic hypotension for other reasons such as sepsis, untreated active cancer, heart failure...

Intervention groups

A group of patients is given oral L-carnitine 1000 mg 30-60 min before dialysis for one month. The second group is given midodrine 5 mg and half an hour before dialysis for one month.

Main outcome variables

Blood pressure changes between before and after dialysis timepoints

General information

Reason for update

This update was made to correct inconsistencies in the original registry entry and to provide a more accurate and complete description of the prespecified and implemented study methodology. First, the allocation status was originally entered as "non-randomized," although the protocol summary within the same original registry record explicitly described the study as a randomized clinical trial using block randomization. Therefore, this internal inconsistency was corrected, and the actual randomization procedure was clarified by specifying 1:1 allocation, blocked randomization with block sizes of 4, 6, and 10, and sequence generation using the Sealed Envelope tool. Second, an upper age limit of 65 years had been entered in the original registry record. This was corrected to "no upper age limit" to accurately reflect the prespecified eligibility criteria, while the minimum eligible age remained 18 years. Third, the description of the L-carnitine intervention was clarified. The original intervention field specified oral L-carnitine 1000 mg for one month but did not adequately specify its timing in relation to dialysis. The description was therefore completed to indicate administration of oral L-carnitine 1000 mg 30–60 minutes before each dialysis session for one month, consistent with the regimen implemented in the study. Finally, the description and assessment time points of the primary outcome were clarified.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231223060507N1**

Registration date: **2024-01-15, 1402/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2026-09-05, 1405/06/14**
Update count: **1**
Registration date
2024-01-15, 1402/10/25

Registrant information
Name
Fatemeh Rohani
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-05, 1402/10/15
Expected recruitment end date
2024-01-20, 1402/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of midodrine with L -carnitine in the treatment of intradialytic hypotension

Public title
Comparison of midodrine with L -carnitine in the treatment of intradialytic hypotension

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Dialysis patients of Namazi and Shahid Faqihi hospitals
At least two months have passed since they started dialysis
Dialyze at least twice a week
In more than 50% of dialysis sessions, intradialytic hypotension according to the variable definition of the plan
Exclusion criteria:
Intradialytic hypotension may be due to other reasons such as sepsis, untreated active cancer, heart failure...

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description
Eligible participants were allocated to the midodrine or L-carnitine group in a 1:1 ratio. A blocked randomization sequence with block sizes of 4, 6, and 10 was generated using the Sealed Envelope online randomization tool.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study is one-sided blind. Patients do not know how the drug is allocated and do not know which group they belong to. The drug allocator does not know about the placement of people in two groups.

Placebo
Not used

Assignment
Parallel

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

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2023-12-26, 1402/10/05

Ethics committee reference number

IR.SUMS.MED.REC.1402.416

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

The amount of blood pressure drop during hemodialysis

Timepoint

Blood pressure was assessed immediately before and within 5 minutes after each hemodialysis session during the one-month treatment period.

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of patient is given midodrine 5 mg a half hours before dialysis for one month

Category

Treatment - Drugs

2

Description

Intervention group: The second group of patients is given oral L-carnitine 1000 mg 30-60 min before dialysis for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital and Shahid Faqihi Hospital

Full name of responsible person

Fatemeh Rohani

Street address

Internal Medicine Department, Namazi Hospital, Namazi Square

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Drfatemehrohani@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempour

Street address

Seventh floor, Shiraz University of Medical Sciences
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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

Dr Fatemeh Rohani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Public use

Under which criteria data/document could be used

There is no obstacle to using the data by mentioning the source.

From where data/document is obtainable

Shiraz university of medical sciences

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

The request for data should be made through the university website.

Comments