

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A comparative study of the effect of sertraline and midodrine in improving blood pressure during hemodialysis in patients with chronic renal failure, a double-blind clinical trial

Protocol summary

Study aim

A comparative study of the effect of sertraline and midodrine in improving blood pressure during hemodialysis in patients with chronic renal failure, a double-blind clinical trial

Design

This crossover double blind clinical trial is performed on 82 patients with hypotension during hemodialysis. Block randomization method will be used for random allocation. For selecting each blocks; statistical software and the block number will be selected.

Settings and conduct

This study was conducted as a crossover clinical trial study with 82 patients who referred to hemodialysis ward of Imam Hossain Hospital of Shahroud. In this study the evaluator and analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients undergoing permanent hemodialysis for at least 3 months, who have experienced hypotension during dialysis in at least 50% of hemodialysis cases; performing at least 3 hours of hemodialysis at least 3 times a week and exclusion criteria: the presence of severe and relatively severe coagulation problems; the presence of chronic lung and liver disease at the same time and the presence of any mental illness that takes SSRI drugs.

Intervention groups

In the first intervention group, 50 mg of sertraline tablets half an hour before the start of dialysis will be administered for 4 weeks, and after a two-week wash out period, 5 mg of midodrine tablets will be administered half an hour before the start of dialysis for 4 weeks. In the second intervention group, 5 mg of midodrine tablets half an hour before the start of dialysis will be administered for 4 weeks, and after a two-week wash out period, 50 mg of sertraline tablets will be administered half an hour before the start of dialysis for 4 weeks.

Main outcome variables

Systolic blood pressure value ; Diastolic blood pressure value ; number of intradialytic hypotension episodes in each group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N29**

Registration date: **2023-10-10, 1402/07/18**

Registration timing: **prospective**

Last update: **2023-10-10, 1402/07/18**

Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

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

A comparative study of the effect of sertraline and midodrine in improving blood pressure during hemodialysis in patients with chronic renal failure, a double-blind clinical trial

Public title

Comparison of the effect of sertraline and midodrine in improving blood pressure during hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing permanent hemodialysis for at least 3 months, who have experienced hypotension during dialysis in at least 50% of hemodialysis cases; Performing at least 3 hours of hemodialysis at least 3 times a week; Stable vital signs; Having informed consent to participate in the research.

Exclusion criteria:

The presence of severe and relatively severe coagulation problems; The presence of chronic lung and liver disease at the same time; The presence of any mental illness that takes SSRI drugs.

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Care provider
- Data analyser

Sample sizeTarget sample size: **82**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two standard systemic blood pressure measurements at an interval of one hour during hemodialysis

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use block. Random unit: individual. Randomization tool: An online randomization website. Sequence building: using block randomization method with block size of 4. Concealing method: using closed and opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, clinical evaluator and analyzer are blinded. The allocation of patients into two groups A and B is done by a qualified nurse who has no aware of the actions performed in the two groups. Clinical

examination and outcome evaluation will be record by a qualified nurse without any information about the type of intervention.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Shahroud University of Medical Sciences

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Shahroud University of Medical Sciences; 7 Tir squer; Shahroud

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Semnan

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3616647555

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.SHMU.REC.1402.081

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

Hypotension of hemodialysis

ICD-10 code

I95.3

ICD-10 code description

Hypotension of hemodialysis

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

Systolic blood pressure value

Timepoint

Once every hour during hemodialysis

Method of measurement

Sphygmomanometer

2**Description**

Diastolic blood pressure value

Timepoint

Once every hour during hemodialysis

Method of measurement

Sphygmomanometer

Secondary outcomes**1****Description**

Number of intradialytic hypotension episodes in each group

Timepoint

Dialysis even sessions

Method of measurement

Observation by educated and qualified nurse

2**Description**

Frequency of adverse drug reactions in each intervention group

Timepoint

From the start to the end of each medication intervention in each group

Method of measurement

Patient interview

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

Intervention group: in the first intervention group, 50 mg of sertraline tablets half an hour before the start of dialysis will be administered for 4 weeks, and after a two-week wash out period, 5 mg of midodrine tablets will be administered half an hour before the start of dialysis for 4 weeks.

Category

Treatment - Drugs

2**Description**

Intervention group: in the second intervention group, 5 mg of midodrine tablets half an hour before the start of dialysis will be administered for 4 weeks, and after a two-week wash out period, 50 mg of sertraline tablets will be administered half an hour before the start of dialysis for 4 weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital of Shahroud

Full name of responsible person

Dr. Hoofer Rafiei

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

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Vice chancellor for research; Shahroud University medical Sciences; 7th Tir squar; Shahroud

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice chancellor for research; Shahroud University medical and 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
Shahroud University of Medical Sciences

Full name of responsible person
Dr. Zahra Amirkhanloo

Position
Resident of Internal Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available