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 Ssciences and Health

Country

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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.
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target 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
Street address
Shahroud University of Medical Sciences; 7 Tir squer; Shahroud
City
Shahroud
Province
Semnan
Postal code
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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Imam Hossein Hospital., End Imam street., Shahroud; Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Mohammad Hasan Imamian
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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
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Person responsible for updating data

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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