Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the efficacy of mirtazapine versus sertraline on depression symptoms in patients undergoing hemodialysis: a double-blind randomized clinical trial

Protocol summary

Study aim
To evaluate the efficacy of mirtazapine versus sertraline on depression symptoms in patients undergoing hemodialysis

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Beheshti Hospital in Hamadan city on 54 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 5 years Undergoing hemodialysis for at least 6 months Being literate Suffering from depression Exclusion criteria: Pregnancy or breastfeeding Receiving anti-depressant and anti-anxiety medication in the last 3 months Liver failure Use of drugs or alcohol

Intervention groups
Intervention group: Tablet mirtazapine 7.5 mg daily for one week and then 15 mg daily for 11 weeks Control group: Tablet sertraline 50 mg daily for one week and then 100 mg daily for 11 weeks

Main outcome variables
Primary outcome: Depression score Secondary outcome: Quality of life score Serum albumin level Percentage of weight gain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N445**
Registration date: **2022-11-09, 1401/08/18**
Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**
Update count: **0**

Registration date
2022-11-09, 1401/08/18

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the efficacy of mirtazapine versus sertraline

on depression symptoms in patients undergoing hemodialysis: a double-blind randomized clinical trial

Public title
Evaluating the efficacy of mirtazapine versus sertraline on depression symptoms in patients undergoing hemodialysis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 5 years Undergoing hemodialysis for at least 6 months Being literate Suffering from depression
Exclusion criteria:
Pregnancy or breastfeeding Receiving anti-depressant and anti-anxiety medication in the last 3 months Liver failure Use of drugs or alcohol
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
Postal code
6517838695
Approval date
2022-10-29, 1401/08/07
Ethics committee reference number
IR.UMSHA.REC.1401.648

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32.8
ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
Depression score
Timepoint
In weeks 4, 8, and 12 after the treatment
Method of measurement
Using the Beck Inventory Questionnaire

Secondary outcomes

1

Description
Quality of life score
Timepoint
After week 12
Method of measurement
Using Global Quality of Life Scale

2

Description
Serum albumin level
Timepoint

After week 12
Method of measurement
By using laboratory test

3

Description
Percentage of weight gain
Timepoint
After week 12
Method of measurement
By using weights

Intervention groups

1

Description
Intervention group: Tablet mirtazapine 7.5 mg daily for one week and then 15 mg daily for 11 weeks
Category
Treatment - Drugs

2

Description
Control group: Tablet sertraline 50 mg daily for one week and then 100 mg daily for 11 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan city
Full name of responsible person
Shadieh Shariati
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Beheshti Hospital, Eram Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Shadieh Shariati
Position
Student of Pharmacology
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Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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

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