

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Feb 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

Country

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

City

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Province

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

Street address

Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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inquiries

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Position

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Medical Pharmacy

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Person responsible for updating data

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Full name of responsible person

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Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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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