

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating The effect of fluoxetine on severity of depressive and anxiety symptoms in hemodialysis patients: a randomized, double blind, placebo controlled clinical trial

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of fluoxetine in controlling the symptoms of anxiety and depression in hemodialysis patients.

Design

This study is a clinical trial with a control group, with parallel groups, double-blind, randomized, phase 4 on 70 patients undergoing hemodialysis with major depression. Patients were randomly assigned to the intervention and control groups by block method.

Settings and conduct

Seventy patients with hemodialysis with depression, if they have a BDI-II score greater than or equal to 16 and meet the inclusion criteria, are randomly assigned to the control and fluoxetine-receiving groups. The study site is Shafa and Javad Al-Aimeh medical centers in Kerman.

Participants/Inclusion and exclusion criteria

Patients undergoing hemodialysis with a diagnosis of major depression based on the DSM with the age of 18 to 80 years who have no other medical or psychiatric illness, no other treatments and have written consent to participate in the study are included in the study.

Intervention groups

Fluoxetine capsules are started at a daily dose of 10 mg and increased to a maximum of 20 mg per day after one week if the patient does not have severe or intolerable side effects.

Main outcome variables

severity of depression severity of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220422054611N1**

Registration date: **2022-05-27, 1401/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-27, 1401/03/06**

Update count: **0**

Registration date

2022-05-27, 1401/03/06

Registrant information

Name

Marjan Shamspour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating The effect of fluoxetine on severity of depressive and anxiety symptoms in hemodialysis patients: a randomized, double blind, placebo controlled clinical trial

Public title

Evaluating The effect of fluoxetine on severity of depressive and anxiety symptoms in hemodialysis patients	
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	People on hemodialysis who have a score greater than or equal to 16 according to the Beck Depression Inventory II (BDI-II) criterion and who have major depression based on a structured clinical interview (based on DSM-V) Age from 18 to 80 years People who have been on hemodialysis for more than three months and undergo regular hemodialysis three times a week No treatment with antidepressant, benzodiazepines, pregabalin or gabapentin in the previous month No treatment with ECT (Electroconvulsive therapy) in the last 2 months Not being treated for psychotherapy during the study Written consent to participate in the study
Exclusion criteria:	History of severe allergic reaction to fluoxetine or intolerable drug side effects Hepatitis B and C and liver failure, history of seizures, uncontrolled thyroid disease, neurological diseases, history of gastrointestinal ulcer (PUD) and gastrointestinal bleeding during the last three months Patients treated with psychiatric drugs as well as taking special drugs such as: warfarin, corticosteroids, triptans, tramadol, Nonsteroidal anti-inflammatory drugs Moderate to severe intellectual disability Patients with a history of dementia Hyponatremia Existence of a serious risk factor for QTc prolongation such as congenital prolonged QT syndrome, long QT history, family history of prolonged QT or sudden cardiac death, hypokalemia, hypomagnesemia, recent heart attack, bradycardia, decompensated heart failure, concomitant use of enzyme inhibitors CYP2D6, use of other QTc prolonging drugs such as metoclopramide, antipsychotics, methadone, erythromycin, fluoroquinolones, fluconazole, etc Patients presented with psychotic feature and having a disorder other than depression such as bipolar disorder, schizophrenia or other psychotic disorders, panic disorder (other anxiety disorders are not excluded), personality disorders, obsessive-compulsive disorder History of stimulants and hallucinogens abuse Pregnant women or women who plan to become pregnant in the next few months Breastfeeding Patients in need of electroconvulsive therapy or in need of hospitalization in a psychiatric center (based on the evaluation and opinion of a psychiatrist) There is a possibility of suicide or a serious desire to commit suicide
Age	From 18 years old to 80 years old
Gender	Both
Phase	4
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	Block randomization method was used in this study.
Blinding (investigator's opinion)	Double blinded
Blinding description	Randomization is hidden from researchers and participants, physicians, nurses, and data collection assistants until the statistical analysis is completed.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics Committee of Kerman University of Medical Sciences
Street address	University of Medical Sciences, Haft Bagh Alavi Highway, Kerman
City	Kerman
Province	Kerman
Postal code	7616913555
Approval date	2022-04-16, 1401/01/27
Ethics committee reference number	IR.KMU.REC.1401.014
Health conditions studied	
1	
Description of health condition studied	Depressive symptoms in hemodialysis patients
ICD-10 code	F32
ICD-10 code description	Major depressive disorder, single episode
2	
Description of health condition studied	Anxiety symptoms in hemodialysis patients
ICD-10 code	F41.1
ICD-10 code description	

Generalized anxiety disorder

Primary outcomes

1

Description

Evaluation of the severity of depression

Timepoint

The assessment of the severity of depression at the beginning of the study and every two weeks for eight weeks

Method of measurement

By the beck depression inventory II questionnaire score and Montgomery-Asberg Depression Rating Scale

Secondary outcomes

1

Description

Evaluation of the severity of anxiety

Timepoint

The assessment of the severity of anxiety at the beginning of the study and every two weeks for eight weeks

Method of measurement

By the Hospital Anxiety and Depression Scale- Anxiety subscale

Intervention groups

1

Description

Intervention group: Intervention group Patients in the intervention group take 10 mg fluoxetine capsules of Abidi company for one week and if the drug is tolerated, 20 mg daily until the end of eight weeks of treatment

Category

Treatment - Drugs

2

Description

Patients in the control group will receive a daily capsule that is quite similar in color and size to fluoxetine but contains an inert substance such as starch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa and Javadalaimeh medical centers in Kerman

Full name of responsible person

Marjan shamspour

Street address

Shafa hospital, Kosar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Askari

Position

Resident of psychiatry

Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

All the potential data can be shared after blinding.

When the data will become available and for how long

Six months after the results were published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Dr Marjan Shamspour m.shamspour@kmu.ac.ir

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

Official letter to the researchers through Email

Comments