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

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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
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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