# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 Jul 2026

## Evaluation and comparison of the effects and complications of escitalopram and citalopram on depression in patients with chronic renal failure undergoing hemodialysis

## Protocol summary

**Study aim**
Evaluation and comparison of the effect and side effects of escitalopram and citalopram on depression in patients with chronic renal failure undergoing hemodialysis

**Design**
a prospective, double-blind rct.that 50 patients with major depressive disorder and chronic renal failure who were undergoing hemodialysis treatment referred to Yazd University Hospitals

**Settings and conduct**
a prospective, double-blind randomized clinical trial .In this study, patients with major depressive disorder and chronic renal failure who were undergoing hemodialysis treatment referred to Yazd University Hospitals were studied.In this study, the patient and the researcher were blinded to the results of the study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:patients with mdd with a minimum depression score of 13 with Hamilton Test and psychiatrist approval, patients with renal failure who were undergoing hemodialysis treatment for at least 3 months, and exclusion criteria:Systemic medical disease that interferes with medication use or follow-up, liver failure, hepatitis B and C, HIV/AIDS, Psychiatric disorder other than depression, patient being treated with SSRIs , pregnancy or lactation, opiate and psychotropic addiction, any unbearable side effects in Is sick.

**Intervention groups**
Initially, the HAMD was completed .After initial evaluation and confirmation of inclusion criteria, they were randomly assigned to either escitalopram or citalopram treatment for 6 weeks.patients were evaluated after 6 weeks of treatment and after completion of HAMD.drug side effects was measured using a questionnaire developed by the researcher

**Main outcome variables**
Comparison and effect of escitalopram and citalopram on depression in patients with chronic renal failure disorder treated with hemodialysis and evaluation of side effects of these two drugs

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200304046698N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **retrospective**

Last update: **2020-04-09, 1399/01/21**
Update count: **0**

**Registration date**
2020-04-09, 1399/01/21

**Registrant information**

**Name**
Mina Ayatollahi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-09-23, 1397/07/01

**Expected recruitment end date**
2019-11-21, 1398/08/30

**Actual recruitment start date**
2019-02-20, 1397/12/01

**Actual recruitment end date**
2019-11-21, 1398/08/30
**Trial completion date**
2020-01-21, 1398/11/01

**Scientific title**
Evaluation and comparison of the effects and complications of escitalopram and citalopram on depression in patients with chronic renal failure undergoing hemodialysis

**Public title**
Effects of escitalopram and Citalopram on Depression in Patients with Chronic Kidney Failure under Hemodialysis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with major depressive disorder with minimum depression score of 13 with Hamilton Test and psychiatrist approval Patients with renal failure who have been undergoing hemodialysis treatment for at least 3 months
**Exclusion criteria:**
Systemic medical disease (heart disease, diabetes, epilepsy, hypertension, thyroid) that interferes with medication use or follow-up. Liver failure, Hepatitis B and C, HIV / AIDS Existence of psychiatric disorder other than depression Patient being treated with SSRIs (if previously treated after 3 months treatment) Pregnancy or lactation Addiction to all kinds of drugs and psychotropics The occurrence of any unbearable side effects in the patient
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **50**
Actual sample size reached: **46**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The present study is a prospective, double-blind, randomized clinical trial. Patients according to the table of random numbers were assigned to receive either escitalopram or citalopram for 6 weeks.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients participating in the design and principal investigator were kept blind to the assigned study groups.As the drugs were selected from a single drug company and in order to double-blind the study, the escitalopram and citalopram tablets were provided by the pharmacist in a completely similar capsules form drug to the patients and distributed to the patients based on the treatment group and with a confidential code.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
IR.SSU.MEDICINE.REC
**Street address**
No. 50, molasadra, ershad eslami street, yazs Town,
**City**
yazd
**Province**
Yazd
**Postal code**
8916864651
**Approval date**
2019-01-25, 1397/11/05
**Ethics committee reference number**
IR.SSU.MEDICINE.REC.1398.115

## Health conditions studied

### 1

**Description of health condition studied**
Major depressive disorder, chronic renal failure
**ICD-10 code**
F34
**ICD-10 code description**
Persistent mood [affective] disorders

## Primary outcomes

### 1

**Description**
Depression score on the Hamilton scale
**Timepoint**
Assessment of Hamilton depression score at baseline and 6 weeks after intervention
**Method of measurement**
Hamilton Depression Inventory

## Secondary outcomes

### 1

**Description**
Drug side effect

**Timepoint**
At baseline (before intervention) and 6 weeks after drug administration
**Method of measurement**
Questionnaire designed by the researcher

## Intervention groups

### 1

**Description**
The intervention group: In this group escitalopram is prescribed .escitalopram dose increased from 5 mg to 10 mg per day. The drugs were selected from Tehran Pharmaceutical Company and in order to double blind study,escitalopram tablets were provided by a pharmacist in capsule form and distributed to patients based on group therapy and confidential code. Patients' follow-up was performed after 6 weeks of treatment and after completing the course of re-treatment, Hamilton test was examined and drug side effects including: dry mouth, nausea, yawning, sweating, agitation, reduction Appetite, constipation, diarrhea, drowsiness, headache and sexual problems, According to the questionnaire was prepared by the researcher was measured.
**Category**
Treatment - Drugs

### 2

**Description**
The control group: In this group citalopram prescribed.The dose of the drug was increased from 10 mg to 20 mg per day.The drugs were selected from the drug company Poursina and in order to double blind study,citalopram tablets were provided by a pharmacist in capsule form and distributed to patients based on group therapy and confidential code.Patients' follow-up was performed after 6 weeks of treatment and after completing the course of re-treatment, Hamilton's test was examined and drug side effects including: dry mouth, nausea, yawning, sweating, agitation, reduction Appetite, constipation, diarrhea, drowsiness, headache and sexual problems, According to the questionnaire was prepared by the researcher was measured.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Sadoughi Hospital of Yazd, Shahid Rahnemoon Hospital
**Full name of responsible person**
mina ayatollahi
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Yazd University of Medical Sciences
**Full name of responsible person**
Dr. Massoud Mirzaei
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**Email**
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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**
Shahid Sadoughi 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**
Yazd University of Medical Sciences
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mina ayatollahi
**Position**
resident
**Latest degree**
Medical doctor

**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