

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the efficacy of sertraline, escitalopram in treatment of depression in patients undergoing chronic hemodialysis

Protocol summary

Study aim

evaluation of SSRI drugs such as Escitalopram and Sertralin on patints with chronic hemodialysis because of less side effects

Design

Group 1: patients undergo treatment with Escitalopram
Group 2: patients undergo treatment with Sertralin
number of patients in each group are 66 patients parallel groups one sided blindness randomized phase 4

Settings and conduct

Site of study : Imam Hossein hospital Study on two groups with chronic hemodialysis according to Beck questionnaire (score above 8) Group 1 undergo treatment with Escitalopram and Group 2 undergo Treatment with Sertralin Comparrison of data after 3 months blindness with person who evaluate results and analyses datas

Participants/Inclusion and exclusion criteria

Depression in chronic hemodialysis patients Consent for study participation Age above 21 another psychologic problems in patients no drug compliance because of drug side effects data defects patients undergo another treatments patients with no follow up

Intervention groups

patients undergo treatment with Escitalopram patients undergo treatment with Sertralin

Main outcome variables

Effectiveness of drugs basis of beck questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210424051066N1**

Registration date: **2021-05-23, 1400/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

Registration date

2021-05-23, 1400/03/02

Registrant information

Name

Mahdieh Miri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2614 5216

Email address

dr.miri2000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of sertraline, escitalopram in treatment of depression in patients undergoing chronic hemodialysis

Public title

efficacy of sertraline, escitalopram in treatment of depression in patients undergoing chronic hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Depression in chronic hemodialysis patients consent for study participation Age above 21

Exclusion criteria:

another psychologice problems in patients no drug compliance because of drug side effects data defects patients undergo another treatments patients with no follow up

Age

From **21 years** old

Gender

Both

Phase

4

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Person who analyses data Person who evaluate results

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran.shahid chamran highway,Yaman Street,Shahid Aarabi Street,Beside Taleqani Street

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2021-01-05, 1399/10/16

Ethics committee reference number

26501

Health conditions studied**1****Description of health condition studied**

depression

ICD-10 code

A01.02

ICD-10 code description

F32

Primary outcomes**1****Description**

Effect of SSRI drugs on Depression

Timepoint

one month- two months- three months

Method of measurement

Beck questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Escitalopram group, 1week under treatment with Escitalopream 10 mg and then increase doses of drug in 3 months to maximum dose of 20mg. Monitorig of patients one,two and three months after Escitalopram administration with Beck questionnaire.

Category

Treatment - Drugs

2**Description**

Intervention group: Sertraline group,1week under treatment with Sertraline 25 mg and then increase doses of drug in 3 months to maximum dose of 200mg. Monitorig of patients one,two and three months after Sertraline administration with Beck questionnaire.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein hospital

Full name of responsible person

Mahdieh Miri

Street address

Tehran, Shahid madani Street, Imam Hossein hospital

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1617763141
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti 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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Sabaghian
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Beck Questionnaire of patients

When the data will become available and for how long

one year after publication

To whom data/document is available

All people

Under which criteria data/document could be used

for scientific use and article refer

From where data/document is obtainable

Dr.Mahdieh Miri in Imam Hosein hospital

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

goal of access to information evaluation causes of request and then permission to access to information

Comments