

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison between citalopram and sertraline efficacy in patients with depression disorder

Protocol summary

Study aim

A comparative study on the efficacy of citalopram and sertraline drugs. A comparison of the side effects of citalopram and sertraline.

Design

For depression disorder diagnosis, all of the patients are visited by psychiatrist. Additionally, the Hamilton Depression Rating Scale (HAMD) is administered to detect the illness severity at baseline. After 13 weeks of treatment by SSRI (citalopram or sertraline), HAMD test is taken to compare the illness severity at baseline and after treatment. To determine the sample size, we use a randomized clinical trial sample size formula where type one (α) and type two errors (β) were 0.05 and 0.20 (power =80%), respectively. Based on a prior study (Sepehrmanesh et al., 2016), we use a standard deviation (SD) of 8.9 and a change in mean (d) of 6.6, considering BDI as the main variable. The calculation indicate 29 patients are needed in each group. Assuming a dropout of 5 patients each group, the final sample size was determined to be 34 patients each group.

Settings and conduct

Ive Sina Psychiatric Hospital Mashhad study will be location. study is single blind.

Participants/Inclusion and exclusion criteria

The inclusion criteria were as follows: depression diagnosis according to diagnosis of the doctor, a total score on the HAMD more than 13 (mild to moderate depression) and age between 18 to 60 years. The exclusion criteria were as follows: epilepsy, liver/renal/heart diseases, other psychological disorder, had never been treated with SSRI, current treatment with other antidepressants and all of CNS drugs from 6 months ago, pregnancy, lactation and addiction.

Intervention groups

1- Citalopram tablet recipients group 2- Sertraline tablet recipients group

Main outcome variables

change of depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171112037407N1**

Registration date: **2017-12-22, 1396/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-22, 1396/10/01**

Update count: **0**

Registration date

2017-12-22, 1396/10/01

Registrant information

Name

Mahnaz Ahmadimanesh

Name of organization / entity

Mashhad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3869 6822

Email address

ahmadimm931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-21, 1395/07/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between citalopram and sertraline efficacy in patients with depression disorder

Public title

Effect of citalopram and sertraline in treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

depression diagnosis according to diagnosis of the doctor a total score on the HAMD more than 13 (mild to moderate depression)

Exclusion criteria:

epilepsy, liver/renal/heart diseases, other psychological disorder had never been treated with SSRI current treatment with other antidepressants and all of CNS drugs from 6 months ago pregnancy and lactation addiction

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

- Care provider

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization assignment was done using computer-generated random numbers and was done by a trained staff at the clinic as blindness

Blinding (investigator's opinion)

Single blinded

Blinding description

Diagnosis of depression and assessment of patients was done without knowledge of the type of intervention group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical sciences

Street address

Azadi

City

Mashhad

Province

Razavi Khorasan

Postal code

91775-1365

Approval date

2016-05-14, 1395/02/25

Ethics committee reference number

IR.MUMS.SP.1395.8

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description

depression score

Timepoint

13 weeks later stat of treatment

Method of measurement

Hamilton Depression Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Citalopram tablet produced by Iranian Factory at dose 20-40 mg/day prescribed to patients

Category

Treatment - Drugs

2

Description

Intervention group: Sertraline tablet produced by Iranian Factory at dose 50-100 mg/day prescribed to patients

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ave Sina hospital

Full name of responsible person

Farhad Farid hoseini

Street address

Bou Ali Square

City

Mashhad

Province

Razavi Khorasan

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91959

Phone

+98 51 3711 2701

Email

Faridhoseinif@mums.ac.ir

2

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Farhad Farid Hoseini

Street address

Emam Reza square

City

Mashhad

Province

Razavi Khorasan

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9137913316

Phone

+98 51 3854 3031

Email

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3

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Fatemeh Behdani

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Ahmad Abad Ave

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99199- 91766

Phone

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Email

Behdanif@mums.ac.ir

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Adel Moallem

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+98 51 3882 3255

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moallem@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amir houshang Mohamadpoor

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sponsors / Funding sources

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amir houshang Mohamadpoor

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of patient information, publication is not allowed.

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

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

Since, this research is performed in the form of a thesis, the entire protocol and the each section design of the study will be provided in a thesis book which will be available in the library of the Mashhad University of Medical Sciences. An article from this study will also be published.

When the data will become available and for how long

1398

To whom data/document is available

Scientific and academic institutions

Under which criteria data/document could be used

nothing

From where data/document is obtainable

thesis and its paper

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

nothing

Comments

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahnaz Ahmadimanesh

Position

Resident

Latest degree

Master

Other areas of specialty/work

Toxicology

Street address

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City

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