Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Postal code
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
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Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
Faridhoseinif@mums.ac.ir

3

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Fatemeh Behdani
Street address
Ahmad Abad Ave
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99199- 91766
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Behdanif@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Adel Moallem
Street address
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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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Person responsible for scientific inquiries

Contact

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Position
Professor

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Person responsible for updating data

Contact

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Mahnaz Ahmadimanesh

Position
Resident

Latest degree
Master

Other areas of specialty/work
Toxicology

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91775-1365

Phone
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Email
Ahmadimm931@mums.ac.ir

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