Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Efficacy of Serteralin add-on therapy to Atypical Antipsychotics on maintenance therapy of schizophrenia patients on depression and level of function: Isfahan 2011-12

Protocol summary

Summary

Main goal:efficay of Sertraline add-on therapy to Atypical antipsychotics in maintenance therapy of Schizophrenia patients .This study is double -blind placebo-control unicentric study . 54 schizophrenia patients (27 in intervention and 27 in control grops) who are in remission according to PANSS questionare were given Sertraline or placebo after informed consent. PANSS ;CDSS ; QLS and GAF questionare were completed at weeks 0,8,12. Inclusion criteria :1-age 16-65; 2-substance abuse or sever medical abuse. exclusion :sever side effects.final goal:adding Sertraline to antipsychotic regimen to decrease depression and increase quality of life and function of this patints.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110187839N1**
Registration date: **2011-11-13, 1390/08/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-11-13, 1390/08/22

Registrant information

Name
Ghadir Mohammad Hoseiny
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2011-11-11, 1390/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Serteralin add-on therapy to Atypical Antipsychotics on maintenance therapy of schizophrenia patients on depression and level of function: Isfahan 2011-12

Public title

Effect of Sertraline on Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1-age:16-65y/o; 2-no substance abuse or sever medical disease; 3-no pregnancy or breast feeding; 4- patients medication should be one of atypical antipsychotics(Risperidone,Olanzapine,Aripiperazole,Quetiapine or Clozapine); 5- the patients are not in acute phase of disease; 6- the patients are on maintenance medication. Exclusion criteria:1-sever side effects; 2-no intrest in patient or his/her family to maintain on the study; 3-pregnancy; 4-drug non-tolerance.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Azadi sq., Isfahan, Iran.

City

isfahan

Postal code

Approval date

2011-05-20, 1390/02/30

Ethics committee reference number

3878/8/12 on 15-5-2011

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

The schizophrenic disorders are characterized in general by fundamental and characteristic distortions of thinking and perception, and affects that are inappropriate or blunted. Clear consciousness and intellectual capacity are usually maintained although

Primary outcomes

1

Description

score of Depression

Timepoint

before starting study and after weeks 8,12

Method of measurement

CDSS(Calgray Depressive Scale of Schizophrenia)

2

Description

score of Quality of Life

Timepoint

before starting study and after weeks 8,12.

Method of measurement

QLS questionare (Quality of life in Schizophrenia)

3

Description

score of Psychosis

Timepoint

before starting study and after weeks 8,12.

Method of measurement

PANSS questionare (Positive And Negative Syndrome Scale)

4

Description

Level of Function

Timepoint

before starting study and after weeks 8,12.

Method of measurement

GAF questionare (Global Assessment of Function)

Secondary outcomes

1

Description

side-effects of medication

Timepoint

weeks 8,12

Method of measurement

quastionare of side effects

Intervention groups

1

Description

Sertraline 50 mg/day was started for intervention group that could rise to 200mg/day gradually.In control group placbo pills that are identical to sertraline was prescribed.Both drug and placebo daily dosage was 1 tablet per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Noor hospital, Isfahan

Full name of responsible person
Miss Qasemi,psychologist

Street address
Noor hospital, Ostandari st., Isfahan, Iran

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Dr.Aazarm

Street address
Isfahan University of Medical Sciences, Azadi sq., Isfahan, Iran

City
Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Isfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Ghadir Mohammad Hoseiny

Position
Resident of Psychiatry

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Victoria Omranifard

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Psychiatrist

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Resident of Psychiatry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty