

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of Typical Antipsychotic Augmentation with Sertraline in Reduction of Negative Symptoms in patients with Schizophrenia in Ahwaz Golestan Hospital

Protocol summary

Summary

The aim of this study was to evaluate the efficacy of sertraline added to typical antipsychotics for the treatment of negative symptoms of patients with schizophrenia disorder. This study is a randomized double blind, with placebo control, unicameral, phase 2 clinical trial. Inclusion criteria for the study: schizophrenia; negative score more than 15 in PANSS. Exclusion criteria for the study: patient withdrew from the study and drug side effects. Number of patients in the study are 30. The efficacy of sertraline and placebo in reduction of social withdrawal, emotional withdrawal, blunted affect and other negative symptoms was assessed weekly with PANSS scale during 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041317246N1**
Registration date: **2014-04-23, 1393/02/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-23, 1393/02/03

Registrant information

Name

Somayeh Raz

Name of organization / entity

Ahwaz Jondishapur University of Medical Science

Country

Iran (Islamic Republic of)

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+98 61 1336 7543

Email address

raz.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology
Development- Ahwaz Jondishapur University of Medical
Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Typical Antipsychotic Augmentation with Sertraline in Reduction of Negative Symptoms in patients with Schizophrenia in Ahwaz Golestan Hospital

Public title

The Effect of Sertraline In Treatment Of Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for this study are as follows: schizophrenia - a negative score more than 15 in PANSS; no liver disease; not treated with ECT in the past six months; during illness for over one year; aged between 21 to 63 years old. The Exclusion criteria are: depression; mental retardation; schizoaffective disorder; bipolar disorder; a neurological disorder such as epilepsy, Parkinson's disease; a risky physical illness such as cardiac ischemia or heart failure; use of antidepressants

or lithium for whatever reason; Leisure drug; drug abuse within one recent month (except nicotine and caffeine); extrapyramidal side effects; deafness or dumbness active suicidal or homicidal thoughts; pregnant or lactating women; at least 3 months have passed since the last time the use of long-acting antipsychotics; drugs with a history of hypersensitivity or serious interest in the study; the patient withdrew from the study and side effects.

Age

From **21 years** old to **63 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Jondishapur University of Medical Sciences

Street address

Ahwaz Jondishapur University of Medical Sciences,
Golestan Blvd

City

Ahwaz

Postal code

6481958956

Approval date

2011-07-27, 1390/05/05

Ethics committee reference number

ETH201

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

Emotional withdrawal

Timepoint

Before intervention, 1 week after intervention, 3 weeks after intervention, 6 weeks after intervention

Method of measurement

PANSS(Positive and Negative Symptom Scale)

2

Description

Social withdrawal

Timepoint

Before intervention, 1 week after intervention, 3 weeks after intervention, 6 weeks after intervention

Method of measurement

PANSS(Positive and Negative Symptom Scale)

3

Description

Blunted affect

Timepoint

Before intervention, 1 week after intervention, 3 weeks after intervention, 6 weeks after intervention

Method of measurement

PANSS(Positive and Negative Symptom Scale)

4

Description

Other negative symptoms

Timepoint

Before intervention, 1 week after intervention, 3 weeks after intervention, 6 weeks after intervention

Method of measurement

PANSS(Positive and Negative Symptom Scale)

Secondary outcomes

1

Description

Side effects

Timepoint

One week after intervention, 3 weeks after intervention, 6 weeks after intervention

Method of measurement

Interview with patient

Intervention groups

1

Description

Sertraline, tab 50 mg, oral, once a day, for 6 weeks

Category

Treatment - Drugs

2

Description

Placebo, tab 50 mg, oral, once a day, for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of psychiatry

Full name of responsible person

Somayeh Raz

Street address

Department of Psychiatry, Golestan Hospital,
Farvardin Av.

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology
Development-Ahwaz Jondishapur University of
Medical Sci

Full name of responsible person

Dr. Nader Saki

Street address

Vice Chancellor for Research and Technology
Development-Ahwaz Jondishapur University of
Medical Sciences

City

Ahwaz

Grant name

ندارد

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology
Development-Ahwaz Jondishapur University of Medical
Sci

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

Ahwaz Jondishapur University of Medical Sciences

Full name of responsible person

Dr. Seyed Moammad Seyed Ghafari Dezfuli

Position

Assistant professor of psychiatry-psychiatrist

Other areas of specialty/work

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Somayeh Raz

Position

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