

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Effect of citalopram as an adjuvant with atypical antipsychotics on psychotic symptoms in chronic schizophrenia

Protocol summary

Study aim

1- Determine the efficacy of citalopram in combination with atypical antipsychotics on positive symptoms in schizophrenic patients. 2- Determine the efficacy of citalopram in combination with atypical antipsychotics on negative symptoms in patients with schizophrenia. 3- Determine the efficacy of citalopram in combination with atypical antipsychotics on the overall severity of clinical symptoms in schizophrenic patients. If positive results are obtained, the citalopram can be used in combination with atypical antipsychotics to increase the improvement of psychotic symptoms (especially negative symptoms) in patients with schizophrenia.

Design

Two arm parallel group randomized trial; double blinded

Settings and conduct

A study will be carried out on the patients with chronic schizophrenia admitted to the Razi Hospital of Urmia and a clinical interview by the psychiatrist. The interviewer and the medical staff will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the patient are: diagnosis of schizophrenia and its chronic course, with at least 5 years of history of the disease; age: 18 to 65 years old, and the absence of significant symptoms of depression (based on the HAM-D score of less than 20). Exclusion criteria are: drug-related disorders and the absence of other severe physical and psychological disease, such as bipolar disorder or dementia.

Intervention groups

Patients are randomly assigned to the Intervention groups with risperidone, 8 mg daily plus citalopram 20 mg daily and the other group with risperidone 8 mg daily plus placebo.

Main outcome variables

Scale for the Assessment of Negative Symptoms (SANS); Scale for the Assessment of Positive Symptoms (SAPS); CGI-G Scale; CGI-S Scale; Hamilton Depression Rating Scale (HAM-D)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040161N1**

Registration date: **2018-09-20, 1397/06/29**

Registration timing: **prospective**

Last update: **2018-09-20, 1397/06/29**

Update count: **0**

Registration date

2018-09-20, 1397/06/29

Registrant information

Name

Hamed Hajizadeh Touri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of citalopram as an adjuvant with atypical antipsychotics on psychotic symptoms in chronic schizophrenia

Public title

Effect of citalopram in schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of Schizophrenia according to DSM5 criteria and clinical interview by psychiatrist Age range 15-65 years Ability to provide informed consent and cooperation with study procedures At least, 5 years history of schizophrenia Participants needed to be currently taking an Atypic antipsychotic agent for 6 month prior to study Based on the HAM-D scale, having a score of less than 20

Exclusion criteria:

Patients under treatment with clozapin Any sever mental disorder(major depressive disorder, psychotic symptoms, manic phase symptoms,...) Renal, hepatic, thyroid, or hematological disorder; and any sever and chronic medical disorder Pregnancy or lactation Individuals on antidepressants treatment for other indications (Tricyclic antidepressant , MAO inhibitor ,Selective serotonin reuptake inhibitor,...)for 1 month prior to randomization Prior history of convulsion , stroke and head trauma History of mental retardation (IQ less than 70) History of substance abuse or dependence within 6months prior to study participation (except nicotine or caffeine dependence)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

For half of sample (15) there will be number one ball and for another half sample there will be number two ball are dropped in the bag and a ball is taken for each patient indicating his group therapy. The citalopram is inserted into the empty capsules And placed in a box (No. 1). Another box (No. 2) contains filled flour capsules as a placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the researcher and the interviewer and physician from the study, after randomization and determination of the intervention group, citalopram and flour (as a placebo) were poured into empty capsules,

and each according to their designated group, these capsules in duration of treatment will be taken. Randomization will also be in ball and bag mode.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Oroumia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd

City

Urmia

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West Azarbaijan

Postal code

5714783734

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.UMSU.REC.1397.029

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

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

Severity of positive and negative symptom of Schizophrenia

Timepoint

Before intervention (first visit) ,the end of the fourth week (second visit),the end of the eighth week (third visit)

Method of measurement

At each visit to the SANS and SAPS testing will be completed

Secondary outcomes

1

Description

Clinical Global Impression-Improvement

Timepoint

End of eight weeks

Method of measurement

CGI Scale

Intervention groups

1

Description

Intervention group: receive an Risperidone 8mg/day plus Citalopram 20mg/day for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: receive an Risperidone 8mg/day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Safar Hamednia

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Razi Hospital, Salmas Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia 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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Safar Hamednia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Hamed Hajizadeh Touri

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

Psychiatrics

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