Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 serotonine 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, afetr 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
Province
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

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Phone
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Email
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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
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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