

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of citalopram as an adjunctive therapy with olanzapine or aripiprazole on the improvement of negative symptoms in patients with chronic schizophrenia in placebo - randomized clinical trial

Protocol summary

Study aim

Determining the effect of citalopram as an adjunctive treatment with olanzapine and aripiprazole in improving negative symptoms in patients with chronic schizophrenia

Design

This study is an 8-week randomized clinical trial conducted on hospitalized individuals diagnosed with schizophrenia in the psychiatric wards of Imam Hossein (AS) Hospital in Karaj.

Settings and conduct

Patients hospitalized in the psychiatric wards of Imam Hossein Hospital in Karaj diagnosed with schizophrenia. Randomized clinical trial using random block design for both treatment groups. Double-blind study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with schizophrenia up to three years ago Age range of participants between 18 and 50 years Based on PANSS and BPRS scores for negative symptoms Exclusion criteria: Individuals with substance abuse disorders Positive response to Hamilton and PANSS questionnaires based on depression confirmation Tendency and decision to commit suicide on the Hamilton scale Patients with any psychiatric disorder other than schizophrenia Patients who have received electroconvulsive therapy in the past 2 weeks and any serious medical or neurological condition, etc.

Intervention groups

In this study, 160 patients are divided into four groups (40 patients in each group): one group is treated with citalopram (up to 40 mg per day) with olanzapine (15 mg dose) and another group is treated with citalopram (up to 40 mg per day) plus aripiprazole (20 mg per day). One group is treated with olanzapine 15 mg per day along with a placebo, and one group is treated with aripiprazole 15-20 mg per day along with a placebo.

Main outcome variables

Citalopram, which is one of the antidepressants with the least drug interactions, is used as an adjunctive drug to improve negative symptoms of schizophrenia along with standard antipsychotic treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221025056289N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

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Name of organization / entity

Alborz university of medical science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-25, 1402/02/05

Expected recruitment end date

2023-06-26, 1402/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of citalopram as an adjunctive therapy with olanzapine or aripiprazole on the improvement of negative symptoms in patients with chronic schizophrenia in placebo - randomized clinical trial

Public title

the effect of citalopram on negative symptoms of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who, based on criteria, have been diagnosed with schizophrenia and are receiving treatment by a psychiatrist in a psychiatric ward up to 3 years after diagnosis. The minimum PANSS score should be 60 in. This score requires a minimum of 20 on the negative symptom subscale and a BPRS score of 41. The age range of participants is between 18 and 50.

Exclusion criteria:

The tendency and decision towards suicide in the Hamilton test. The tendency and decision towards suicide in the Hamilton test. Individuals with a score greater than 14 based on the 17-item Hamilton Depression Rating Scale (HDRS), or meeting major depression criteria, or having a score of above 4 on all but the depression item of the PANAS. Patients diagnosed with any type of non-schizophrenic mental disorder, especially bipolar disorder, schizoaffective disorder, and individuals with major depressive disorders that have been identified by a psychiatric interview. In addition, patients who have received electroconvulsive therapy (ECT) in the past 2 weeks are not eligible to participate in this study. Any serious or neurological medical condition, pregnancy or lactation, pregnant women without contraception, patients with Class IV and III heart failure, drug or insulin-dependent diabetes, liver disease, or congestive heart failure are not eligible for the study.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual randomization will be performed using a four-block randomization scheme. The random sequence will

be generated using STATA software and random numbers. In addition, to ensure randomization concealment, opaque, sealed envelopes will be used, which will be marked with a 5-digit random number sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients and the therapist will be blinded to the randomization assignment (double-blind).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Alborz University of Medical Sciences

Street address

Alborz University of Medical Science, Official settlement, North Taleghani boulevard, Taleghani Square, Karaj, Alborz Province

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karaj

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3147734568

Approval date

2023-02-19, 1401/11/30

Ethics committee reference number

IR.ABZUMS.REC.1401.326

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

Schizophrenia

ICD-10 code

F20.9

ICD-10 code description

Schizophrenia, unspecified

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

Negative symptoms in patients with chronic schizophrenia

Timepoint

In this study, negative symptoms of schizophrenia will be assessed in the beginning, 4th week and at the end of the 8th week of the clinical trial.

Method of measurement

The PANSS-BPRS questionnaire and the Hamilton questionnaire.

Secondary outcomes

1

Description

Positive symptoms of patient with chronic schizophrenia

Timepoint

In this study, negative symptoms of schizophrenia will be assessed in the beginning, 4th week and at the end of the 8th week of the clinical trial.

Method of measurement

Diagnosis based on DSM-5 criteria, PANSS-BPRS questionnaire.

Intervention groups

1

Description

Intervention group: Under treatment with citalopram (up to 40 milligrams per day) and olanzapine (dose of 15 milligrams).

Category

Treatment - Drugs

2

Description

Intervention group: Under treatment with Citalopram (maximum of 40 milligrams per day) in addition to Aripiprazole (20 milligrams per day).

Category

Treatment - Drugs

3

Description

Control group: Under treatment with 15 milligrams per day of olanzapine accompanied by medication schedule.

Category

Placebo

4

Description

Control group: Under treatment with Aripiprazole, 15 to 20 milligrams per day, accompanied by medication schedule.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Atefe Zandifar

Street address

Imam Hossein Hospital, Mansoorbakht Street, Mohammad Shahr, Alborz province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Science

Full name of responsible person

The assistant of research and technology of Alborz University of Medical Science; Dr Lotfi

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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

Alborz University of Medical Science

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

Alborz university of medical sciences

Full name of responsible person

Saeideh Mahmoudnia

Position

Intern of medicine

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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

The data won't be released until the publication of the study.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available