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
Saeideh Mahmoudnia
Name of organization / entity
Alborz university of medical science
Country
Iran (Islamic Republic of)
Phone
+98 919 560 3128
Email address
mahmoudniasaeideh@gmail.com

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
City
karaj
Province
Alborz
Postal code
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

City

Mohammadshahr

Province

Alborz

Postal code

3147734568

Phone

+98 26 3419 3000

Fax

Email

zandifaratefe@gmail.com

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 Sciensce; Dr Lotfi

Street address

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

City

karaj

Province

Alborz

Postal code

3147734568

Phone

+98 26 3255 8920

Email

zandifaratefe@gmail.com

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

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

City
karaj

Province
Alborz

Postal code
3185746957

Phone
+98 26 3340 1629

Email
mahmoudniasaeideh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Alborz university of medical sciences

Full name of responsible person
Atefe Zandifar

Position
Associate professor, Psychiatrist

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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

City
karaj

Province
Alborz

Postal code
3147734568

Phone
+98 26 3255 8920

Email
zandifaratefe@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Alborz university of medical sciences

Full name of responsible person
Saeideh Mahmoudnia

Position
Medical doctor

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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

City
karaj

Province
Alborz

Postal code
3185746957

Phone
+98 26 3340 1629

Email
mahmoudniasaeideh@gmail.com

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