

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparative Effect of Citalopram and Escitalopram in the Management of Depressive Symptoms among Patients with Schizophrenia

Protocol summary

Study aim

Comparative Effect of Citalopram vs. Escitalopram in the Management of Depressive Symptoms among Patients with Schizophrenia

Design

A randomized clinical trial without control group, with parallel groups, blindness, 60 patients randomly divided into two groups of 30 subjects with block sizes of 4 and 6.

Settings and conduct

The population of this study was aged 18< years old who referred to Yahyanezhad Hospital in Babol. Patients are randomly divided into two Intervention groups. En Intervention group: Treatment with citalopram (Ramofarmine Co) started at 10 mg and gradually increased to 40 mg daily. Intervention group2: Treatment with Sitalopram (Abidi Co) at a dose of 5 mg and gradually increased to a dose of 20 mg daily.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of schizophrenia based on DSM-IV TR structured clinical interview by a psychiatrist (faculty member and psychiatry resident) Diagnosis of depression based on DSM-IV TR structured clinical interview by a psychiatrist (faculty member and psychiatry resident) Exclusion Criteria: Drug abuse, Epilepsy, Ischemia Heart Disease, Heart Failure, Mental retardation, Parkinson

Intervention groups

Intervention group1: Treatment with citalopram (Ramofarmine Co) started at 10 mg and gradually increased to 40 mg daily. Intervention group2: Treatment with Sitalopram (Abidi Co) at a dose of 5 mg and gradually increased to a dose of 20 mg daily.

Main outcome variables

patient's depressive condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043700N1**
Registration date: **2019-10-11, 1398/07/19**
Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

Romina Hamzhepour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1951

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2019-09-21, 1398/06/30

Trial completion date

2019-09-21, 1398/06/30

Scientific title

Comparative Effect of Citalopram and Escitalopram in the Management of Depressive Symptoms among Patients with Schizophrenia

Public title

Comparative Effect of Citalopram and Escitalopram in the Patients with Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of schizophrenia based on DSM-IV TR structured clinical interview by a psychiatrist (faculty member and psychiatry resident) Diagnosis of depression based on DSM-IV TR structured clinical interview by a psychiatrist (faculty member and psychiatry resident)

Exclusion criteria:

Drug abuse Epilepsy Ischemia Heart Disease Heart Failure Mental retardation Parkinson

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly divided into two groups of 20 subjects with four and six blocks and an allocation ratio of 1: 1. The participants allocation sequence in two groups performed with a Randomizer software. Opaque sealed sequentially numbered envelopes used for allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the researcher and the patients from the study, after randomization, opaque sealed sequentially numbered envelopes used for allocation concealment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The Ethics Committee of Babol University of Medical

Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

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Babol

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Mazandaran

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4717647745

Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.293

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

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2**Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

patient's depressive condition

Timepoint

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

Method of measurement

(Calgary Depression Scale for Schizophrenia (CDSS))

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Treatment with citalopram (Ramofarmine Co) started at 10 mg and gradually increased to 40 mg daily.

Category

Treatment - Drugs

2

Description

Intervention group2: Treatment with Sitalopram (Abidi Co) at a dose of 5 mg and gradually increased to a dose of 20 mg daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanezhed Hospital

Full name of responsible person

Romina Hamzehpour

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Shahid Mostafa Khomeini St., Modarres St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Romina Hamzehpour

Position

Assistant Professor

Latest degree

Specialist

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

No more information

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