

# 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

r.hamzhepour@mubabol.ac.ir

##### 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

**City**

Babol

**Province**

Mazandaran

**Postal code**

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

##### Street address

Shahid Mostafa Khomeini St., Modarres St

##### City

Babol

##### Province

Mazandaran

##### Postal code

4713566547

##### Phone

+98 11 3222 5035

##### Email

r.hamzehpour@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Reza Ghadimi

##### Street address

Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

4713566547

##### Phone

+98 11 3219 7667

##### Email

rezaghadimi@yahoo.com

#### 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

##### Street address

Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

4713566547

##### Phone

+98 11 3233 8301

##### Email

r.hamzehpour@mubabol.ac.ir

## Person responsible for scientific 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

##### Street address

Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

4713566547

##### Phone

+98 11 3233 8301

**Email**

r.hamzehpour@mubabol.ac.ir

**Person responsible for updating data****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

**Street address**

Babol University Of Medical Sciences, Daneshgah  
Square, Ganjafrooz Avenue

**City**

Babol

**Province**

Mazandaran

**Postal code**

4713566547

**Phone**

+98 11 3233 3308

**Email**

r.hamzehpour@mubabol.ac.ir

**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