# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of adding Cilostazol on cognitive deficits and symptoms of schizophrenic patients: a double-blind, randomized clinical trial

## Protocol summary

**Study aim**

The effect of adding Cilostazol to Treatment of Schizophrenic Patients in the cognition and Symptoms of Disease

**Design**

A double-blind, randomized clinical trial that is conducted on two groups of intervention and control including 60 patients with schizophrenia. Patients are followed for 8 weeks

**Settings and conduct**

The study is conducted at Ebne-sina Psychiatric Hospital in Mashhad. The study is double-blinded, the form of drug and placebo is the same, the rater and the patients are not aware of what treatment they are using. The drug is identified by the pharmacist in sealed envelopes with a numerical code.

**Participants/Inclusion and exclusion criteria**

60 schizophrenic patients inclusion criteria: 1) Diagnosis of schizophrenia based on DSM-5 criteria. 2) aged 18-64 years. 3) Completion of the consent form by the patient or his family. 4) level of education at least 8th grade. exclusion criteria: 1) Simultaneous psychiatric disorders. 2) Hepatic impairment (ALT and AST> 2.5ULN) 3) medical illness. 4) Use of substances other than cigarettes. 5) A hypersensitivity reaction or any intolerable side effects caused by the drugs. 6) Use of other interfering drugs. 7) Serious cognitive impairment. 8) Platelet problem with anticoagulant blood.

**Intervention groups**

In one group as double-blind, Cilostazol is given as a 25 mg dose twice a day for 2 weeks, then 50 mg for 6 weeks, and the other one is given placebo as in the intervention group, twice a day for 8 weeks

**Main outcome variables**

This study could lead to the introduction of auxiliary drug to complement the treatment of symptoms of schizophrenia and its cognitive impairment, with less complications

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180307038989N1**
Registration date: **2018-04-15, 1397/01/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-15, 1397/01/26**
Update count: **0**

**Registration date**

2018-04-15, 1397/01/26

**Registrant information**

**Name**

Maryam Naghibi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3846 7502

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-04-05, 1397/01/16

**Expected recruitment end date**

2018-09-06, 1397/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of adding Cilostazol on cognitive deficits and symptoms of schizophrenic patients: a double-blind, randomized clinical trial

**Public title**
Effect of cilostazol on Schizophrenia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of schizophrenia based on DSM-5 criteria aged 18-64 years completed consent form by the patient or his family at least the eighth grade education
**Exclusion criteria:**
Simultaneous psychiatric disorders liver disorders medical illness Use of opioid substances other than cigarettes A hypersensitivity reaction or any untoward side effects caused by the drug Use of other interfering drugs Serious cognitive impairment blood or Platelet problem Contradictory with taking medication
**Age**
From **18 years** old to **64 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients who completed entry and exit conditions in the study based on random numbers table were randomly assigned to two groups of drugs and placebo
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The study is double blind: the form of drug and placebo is the same, and the evaluator, the patient and the analyst are not aware of what treatment they are using, and drug intervention is identified by the pharmacist in sealed envelopes with a numeric code.
**Placebo**
Used
**Assignment**
Factorial
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
ethics committee of Mashhad university of medical sciences
**Street address**
ghoreishi department, daneshgah ave, Mashhad
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9175845643
**Approval date**
2017-10-08, 1396/07/16
**Ethics committee reference number**
960175

## Health conditions studied

**1**

**Description of health condition studied**
Schizophrenia
**ICD-10 code**
F20
**ICD-10 code description**
Schizophrenia

## Primary outcomes

**1**

**Description**
Score in PANSS questionnaire
**Timepoint**
Before starting the study and at times, 0, 2, 4 and 8 weeks after starting treatment
**Method of measurement**
Schizophrenia symptoms assessment questionnaire PANSS

**2**

**Description**
Memory score in digit span
**Timepoint**
Before starting the study and at times, 0, 2, 4 and 8 weeks after starting treatment
**Method of measurement**
Digit span questionnaire

**3**

**Description**
Cognition scoring based on Wisconsin card sorting test
**Timepoint**
Before starting the study and at times, 0, 2, 4 and 8 weeks after starting treatment
**Method of measurement**
Wisconsin card sorting test

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Cilostazol tablets are orally administered at a dose of 25 mg twice daily for 2 weeks and then 50 mg twice daily for 6 weeks.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: placebo tablets similar to Cilostazol are orally administered at a dose of 25 mg twice daily for 2 weeks and then 50 mg twice daily for 6 weeks.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ebne-sina hospital
**Full name of responsible person**
Mohammadreza Fayyazi Bordbar
**Street address**
Ebne-sina hospitah, hoorre ameli street, Mashhad, Iran
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naghibiM941@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Mohammadreza Fayyazi Bordbar
**Street address**
Ebne-sina research center, Horre ameli street, Mashhad
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fayyazimr@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Mohammadreza Fayyazi Bordbar
**Position**
assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Psychiatrics
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Ebne-sina hospital research center, Horre ameli avenue, Mashhad
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## Person responsible for scientific inquiries

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Specialist

**Other areas of specialty/work**
Psychiatrics

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## Person responsible for updating data

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Maryam Naghibi

**Position**
Assistant

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**Other areas of specialty/work**
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**Fax**

**Email**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is 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

**Title and more details about the data/document**
The total individual participants' data and the results of the study after the deidentification of the individuals are shared.

**When the data will become available and for how long**
starting in April 2019

**To whom data/document is available**
All researchers are able to access the study results

**Under which criteria data/document could be used**
Unidentifiable information is not shared with another organization

**From where data/document is obtainable**
Unidentifiable information is not available to applicants

**What processes are involved for a request to access data/document**
Study data is published in the course of the paper and no other personal data is available to applicants

**Comments**