

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

naghibim941@mums.ac.ir

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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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