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)

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+98 51 3846 7502

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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
City
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9195983134
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naghibiM941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Mohammadreza Fayyazi Bordbar
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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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Latest degree
Specialist

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Psychiatrics

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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