Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Palmitoylethanolamide as adjuvant therapy in the treatment of negative symptoms in patients with chronic schizophrenia: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim
The effect of Palmitoylethanolamide on the treatment of negative symptoms in patients with chronic schizophrenia

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be performed on patients with chronic schizophrenia attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 to 60 years old; take Risperidone for at least 4 weeks at the dose of 4-6 mg/day before entering the study; the positive and acute symptoms of patients should be stable. Exclusion criteria: head trauma; history of shock therapy during past three months prior to the trial; undergoing neurosurgery; presence of acute or chronic systemic diseases; history of allergy to Cilostazol.

Intervention groups
Patients with chronic schizophrenia (based on DSM-5 diagnostic criteria) are included in the study and divided into two control groups (25 participants) and intervention (25 participants). Patients in the intervention group receive Palmitoylethanolamide capsules for eight weeks, and patients in the control group receive placebo for eight weeks. Using Positive and Negative Symptoms Scale (PANSS), patients' negative symptoms are evaluated at weeks 0, 4 and 8.

Main outcome variables
Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N127**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **prospective**

Last update: **2020-05-18, 1399/02/29**
Update count: **0**

Registration date
2020-05-18, 1399/02/29

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Palmitoylethanolamide as adjuvant therapy in the

treatment of negative symptoms in patients with chronic schizophrenia: A randomized double blind and placebo controlled clinical trial

Public title
The effect of Palmitoylethanolamide on the treatment of negative symptoms in patients with chronic schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 60 years Take Risperidone for at least 4 weeks at the dose of 4-6 mg/day before entering the study The positive and acute symptoms of patients should be stable
Exclusion criteria:
Head trauma History of shock therapy during past three months prior to the trial Undergoing neurosurgery Presence of acute or chronic systemic diseases History of allergy to Cilostazol
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.
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1417653761
Approval date
2019-12-28, 1398/10/07
Ethics committee reference number
IR.TUMS.VCR.REC.1398.1002

Health conditions studied

1

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

Primary outcomes

1

Description
Severity of schizophrenia
Timepoint
Baseline and weeks 4 and 8
Method of measurement
By Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Palmitoylethanolamide capsule (ACECR, Tehran), 600 mg, BID, for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo (BID) for 8 weeks

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh hospital
Full name of responsible person
Prof. Mohammad Reza Mohammadi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
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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
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data will be distributed through final report
When the data will become available and for how long
5 years from 2021 to 2026
To whom data/document is available
academic researchers
Under which criteria data/document could be used
users should cite the resource of data
From where data/document is obtainable
Prof Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments