

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)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

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.

City

Tehran

Province

Tehran

Postal code

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

Street address

Roozbeh Hospital, South Kargar Street

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

Email

mohammadimr@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street addressTehran University of Medical Sciences, Qhods St.,
Keshavarz Blvd.**City**

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8898 7381

Email

msahrai@tums.ac.ir

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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Roozbeh Hospital, South Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

Email

s.akhond@sina.tums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Roozbeh Hospital, South Kargar Street, Tehran

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

Email

s.akhond@sina.tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Roozbeh Hospital, South Kargar Street

City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

Fax

+98 21 5541 9113

Email

s.akhond@sina.tums.ac.ir

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