Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Palmitoylethanolamide as adjuvant therapy in the treatment of major depression: a randomised and double blind study

Protocol summary

Summary

The purpose of the present investigation is to assess the efficacy of palmitoylethanolamide as an adjuvant agent in the treatment of major depression in a six-week double-blind, placebo controlled trial. 50 adult outpatients who meet the DSM- 5 criteria for major depression will participate in the trial. Patients who have a baseline Hamilton Rating Scale for Depression score of at least 19 will be allocated into two groups. 25 patients will receive Citalopram 40 mg/day plus palmitoylethanolamide 600mg BID and 25 participants will receive Citalopram 40 mg/day plus placebo. Patients were assessed by a psychiatrist at baseline and after 2, 4 and 6 weeks after the medication started. Depression severity will be assessed by Hamilton Depression Rating Scale which will be the primary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702181556N97**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-02-20, 1395/12/02

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

Tehran University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2019-03-05, 1397/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Palmitoylethanolamide as adjuvant therapy in the treatment of major depression: a randomised and double blind study

Public title

Palmitoylethanolamide in the treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of Major Depressive Disorder based on DSM-5 criteria; baseline Hamilton Depression Rating Scale (HAM-D) (17-item) score of at least 19. Exclusion criteria: presence of psychosis, any other diagnosis in axis I and II; receiving psychotropic medications; receiving any antidepressants during past one month or ECT during past two months; presence of hypothyroidism or cardiovascular problems, pregnancy or nursing women.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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, Keshvarz Blvd.

City

Tehran

Postal code

Approval date

2017-02-03, 1395/11/15

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1624

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major Depressive Disorder

Primary outcomes

1

Description

Severity of depression

Timepoint

Baseline and weeks 2,4 and 6

Method of measurement

by Hamiltion Depression Rating Scale 17-Item

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Citalopram 40 mg/day plus Capsule palmitoylethanolamide 600 mg BID as intervention group for 6 weeks

Category

Treatment - Drugs

2

Description

Tablet Citalopram 40 mg/day plus Capsule placebo as control group for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Sreeet

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

Tehran University of Medical Sciences, Keshvarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty