

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of Palmitoylethanolamide on acute phase of mania: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim

Investigating the effect of Palmitoylethanolamide on the treatment of acute phase of mania

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed among patients who are in the acute phase of mania referred to Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Meeting the DSM-IV criteria for Bipolar Disorder-manic episode - Age between 18 to 54 years old - Score of at least 20 on Young Mania Rating Scale.

Exclusion criteria: Hyper- or hypothyroidism - Substance dependence (except Nicotine and Caffeine) - IQ lower than 70 - Lactating or pregnant women - Severe hepatic disease

Intervention groups

Intervention group: Patients treated with lithium 900mg and risperidone 3mg and Palmitoylethanolamide 600mg twice per day. Control group: Patients treated with lithium 900mg and risperidone 3mg and Placebo twice per day.

Main outcome variables

Severity of mania

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N135**

Registration date: **2021-05-03, 1400/02/13**

Registration timing: **prospective**

Last update: **2021-05-03, 1400/02/13**

Update count: **0**

Registration date

2021-05-03, 1400/02/13

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

2021-05-22, 1400/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Palmitoylethanolamide on acute phase of mania: A randomized double blind and placebo controlled clinical trial

Public title

The effect of Palmitoylethanolamide on the treatment of mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Meeting the DSM-IV criteria for Bipolar Disorder-manic episode Age between 18 to 54 years old Score of at least 20 on Young Mania Rating Scale

Exclusion criteria:

Hyper- or hypothyroidism Substance dependence (except Nicotine and Caffeine) IQ lower than 70 Lactating or pregnant women Severe hepatic disease

Age

From **18 years** old to **54 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

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

2020-11-28, 1399/09/08

Ethics committee reference number

IR.TUMS.DDRI.REC.1399.052

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Severity of mania

Timepoint

Baseline and weeks: 2, 4, 6

Method of measurement

Using Young Mania Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients treated with lithium 900mg and risperidone 3mg and Palmitoylethanolamide 600mg twice per day.

Category

Treatment - Drugs

2

Description

Control group: Patients treated with lithium 900mg and risperidone 3mg and Placebo twice per day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roazbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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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 address

Tehran University of Medical Sciences, Qhods St.,
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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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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 2022 to 2027

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