Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Roozbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi
Street address
Roozbeh Hospital, South Kargar Street, Tehran
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 address
Tehran 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, Tehran
City

Tehran

Province

Tehran

Postal code

1333715914

Phone

+98 21 5541 2222

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 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