

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of melatonin as an adjunct in the treatment of acute mania :A double blind and placebo controlled trial

Protocol summary

Summary

The aim of the present study is to assess the efficacy of Melatonin as an adjuvant agent in the treatment of bipolar disorder (mania episode) in a six-week double-blind, placebo controlled trial. 50 patients with mania hospitalized in Roozbeh Hospitals who meet inclusion criteria will participate in the trial. Patients will be randomly allocated into two groups. The first group (25 patients) will receive Lithium Carbonate 900 mg/day and Risperidone 3 mg/day plus Melatonin 6 mg per day; the second group (25 patients) will receive Lithium Carbonate 900 mg/day and Risperidone 3 mg/day plus placebo. Severity of mania and extrapyramidal side effects will be assessed by Young Mania Rating Scale and Extrapyramidal Symptoms Rating Scale (ESRS) at baseline and after 1, 2, 4 and 6 weeks after the trial started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705181556N98**

Registration date: **2017-05-20, 1396/02/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-20, 1396/02/30

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of melatonin as an adjunct in the treatment of acute mania :A double blind and placebo controlled trial

Public title

Efficacy of melatonin as an adjunct in the treatment of acute mania

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: meeting the DSM-5 criteria for Bipolar Disorder; age between 18 and 65 years; a score of at least 20 points on the Young Mania Rating Scale.

Exclusion criteria: hyper- or hypothyroidism; substance dependence (except for Nicotine and caffeine); IQ lower than 70; history of allergy to lithium, risperidone and melatonin; lactating or pregnant women; receiving medications causing manic like symptoms including stimulants; cardiac conducting disturbance; serious risk of suicide.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

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

Keshvarz Blvd

City

Tehran

Postal code

Approval date

2017-05-13, 1396/02/23

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2136

Health conditions studied

1

Description of health condition studied

Bipolar Disorder

ICD-10 code

F31

ICD-10 code description

Mania episode

Primary outcomes

1

Description

Severity of mania

Timepoint

Baseline and weerks 1, 2, 4, 6

Method of measurement

by Young Mania Rating Scale

Secondary outcomes

1

Description

Severity of extrapyramidal side effects

Timepoint

Baseline and weerks 1, 2, 4, 6

Method of measurement

By Extrapyramidal Symptom Rating Scale(ESRS)

Intervention groups

1

Description

Intervention group: Lithium Carbonate 900 mg/day and risperidone 3mg per day plus melatonin 6 mg/day for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Lithium Carbonate 900 mg/day and risperidone 3mg/day plus placebo 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 Sreet

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
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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