Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of melatium on prevention of relapse in patients with bipolar disorder compared with placebo

Protocol summary

Study aim
Study of the effect of melatium on prevention of relapse in patients with bipolar disorder compared with placebo

Design
This study is a randomized double-blinded clinical trial with a parallel design and a control group. In this randomized study, Phase 3 will be performed on 104 patients diagnosed with bipolar disorder. Random blocking is used for randomization and participants are assigned to two intervention and control groups.

Settings and conduct
This study, which will be conducted in Farabi hospital of Kermanshah, is double-blind one in that way the experimenter and patients do not know how the patient will treat and grouping . Assignment of patients to the two treatment groups will be done by the project partner. Also, patient visits will be performed at follow-up times by the project partner who is not aware of the patient grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 60 years; No history of chronic physical illness such as diabetes; Cardiovascular diseases, respiratory diseases and thyroid diseases; Satisfaction of patients to participate in the study; At least middle school degree; At least one year has passed since the initial diagnosis of the disease
Exclusion criteria: Sleep disorders; Simultaneously receive other non-therapeutic treatments; Chronic mental disorders, especially personality disorders based on a psychiatrist interview; Addiction to drugs; Severe side effects of the drug; Patients who need hospitalization

Intervention groups
The intervention group will receive 30 capsules of melatium (effective ingredients are 3 mg of melatonin and 600 mg of lithium per standardized capsule) every 24 hours for 12 weeks. The control group will receive 30 placebo capsules (starch with 600 mg of lithium) every 24 hours for 12 weeks.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N158**
Registration date: **2020-12-30, 1399/10/10**
Registration timing: **prospective**

Last update: **2020-12-30, 1399/10/10**
Update count: **0**

Registration date
2020-12-30, 1399/10/10

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 1821 4653

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fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-12-31, 1400/10/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of melatium on prevention of relapse in patients with bipolar disorder compared with placebo

Public title

Study of the effect of melatium on prevention of relapse in patients with bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 60 years No history of chronic physical illness such as diabetes Cardiovascular diseases, respiratory diseases and thyroid diseases Satisfaction of patients to participate in the study At least middle School degree At least one year has passed since the initial diagnosis of the disease

Exclusion criteria:

Sleep disorders Simultaneously receive other non-therapeutic treatments Chronic mental disorders, especially personality disorders based on a psychiatrist interview Addiction to drugs Severe side effects of the drug; Patients who need hospitalization

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random blocking. 26 blocks (10 blocks of 10 people, 8 blocks of 8 people, 6 blocks of 6 people, and two blocks of 2 people) will be determined and people will be randomly divided into two intervention and control groups .

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the experimenter and the subject do not know which study group (intervention or control) the patient is in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

ir.kums.rec.1399.753

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

sleep quality

Timepoint

Weeks 3, 6, 9 and after the intervention

Method of measurement

Based on sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive 30 capsules of melatium (effective ingredients are 3 mg of melatonin and 600 mg of lithium per standardized capsule) every 24 hours for 12 weeks.

Category

Treatment - Drugs

2

Description
The control group will receive 30 placebo capsules (starch with 600 mg of lithium) every 24 hours for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Dr. Habibollah Khazaei
Street address
Farabi Hospital, Dolatabad Blvd, Isar Square
City
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6719851151
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Reza Khodarahmi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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rkhodarahmi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Habibollah Khazaei
Position
Faculty member of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document

Documentation will be emailed within a 25-day timeframe

Comments