

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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)

Phone

+98 83 1821 4653

Email address

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

Kermanshah

Province

Kermanshah

Postal code

6719851151

Phone

+98 83 8216 0700

Email

hakhazaie@gmail.com

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

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

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

Street address

Farabi Hospital, Dolatabad Blvd, Isar Square

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Person responsible for updating data

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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