

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of melatonin versus placebo on the sleep improvement and quality of life in patients with bipolar disorder in the manic phase: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of melatonin versus placebo on the sleep improvement and quality of life in patients with bipolar disorder in the manic phase

Design

This is a double-blind randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with bipolar disorder in the manic phase who will refer to Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Bipolar disorder in the manic phase Exclusion criteria: Panic disorder or social phobia, Depressive disorder, Schizophrenia, Alcohol or drug abuse, History of suicide in the past year

Intervention groups

Intervention group: Routine treatment plus melatonin tablets manufactured by Jaius Company 30 mg every night for one week and then 60 mg every night for three weeks Control group: Routine treatment plus placebo tablets manufactured by the School of Pharmacy, Hamadan University of Medical Sciences, one tablet every night for one week and then two tablets every night for three weeks

Main outcome variables

Primary outcome: Quality of sleep, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N314**

Registration date: **2019-10-29, 1398/08/07**

Registration timing: **prospective**

Last update: **2019-10-29, 1398/08/07**

Update count: **0**

Registration date

2019-10-29, 1398/08/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-12, 1398/08/21

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin versus placebo on the sleep improvement and quality of life in patients with bipolar disorder in the manic phase: a double-blind randomized clinical trial

Public title

Effect of melatonin versus placebo on the sleep improvement and quality of life in patients with bipolar disorder in the manic phase

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years, Bipolar disorder in manic phase

Exclusion criteria:

Panic disorder or social phobia, Depressive disorder, Schizophrenia, Alcohol or drug abuse, History of suicide in the past year

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.UMSHA.REC.1398.609

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

Quality of sleep

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

By Insomnia Severity Index (ISI)

2

Description

Quality of life

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

By Young Mania Rating Scale (YMRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus melatonin tablets manufactured by Jaius Company 30 mg every night for one week and then 60 mg every night for three weeks

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus placebo tablets manufactured by the School of Pharmacy, Hamadan University of Medical Sciences, one tablet every night for one week and then two tablets every night for three weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Zahra Ghasemian

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Ghasemian

Position

Pharmacy Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

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Pharmacologist

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Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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