Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Jairus 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)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

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 Jairus 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.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3827 4184

Email
zahraghasemian758@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Saeid Bashirian

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0717

Email
info.research@umsha.ac.ir

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

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

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
zahraghasemian758@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Davood Ahmadimoghadam

Position
Pharmacologist

Latest degree
Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

d.ahmadimoghadam@umsha.ac.ir

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

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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