

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of melatonin on circadian rest-activity rhythms during benzodiazepine tapering in patients with bipolar disorder and comparing it with the control group

Protocol summary

Study aim

The aim of this study was to investigate the effect of melatonin on circadian rest-activity rhythms during benzodiazepine tapering in bipolar patients and comparing it with the control group

Design

Clinical trial with the control group, with parallel groups, single-blind, randomized, phase 3 on 33 participants in each group. block randomized used for randomization.

Settings and conduct

This study conducted at Baharan hospital in Zahedan, patients with bipolar disorder randomized into the intervention and control group. patients blinded to their treatment.

Participants/Inclusion and exclusion criteria

Participants eligible for the trial were 18 years or above; had a diagnosis of bipolar mood disorder; were treated with at least one antipsychotic drug, and had a daily use of at least one benzodiazepine for a minimum of 3 months. Participate present with current violent or aggressive behavior; diagnosed with mental retardation, pervasive developmental disorder, dementia, hepatic impairment, terminal illness, severe somatic comorbidity, or epilepsy; had allergic to any compounds in the study medication; breastfeeding women; patients who had a comorbid mental disorder; opioid or any drug use and lack of informed consent excluded from the study.

Intervention groups

Melatonin group: 2 mg once daily for 3 days, and in parallel they were instructed to gradually reduce their daily benzodiazepine usage. Participants ingested the medication approximately 2 h before bedtime with a small meal. Placebo group: 2 mg once daily for 3 days, and in parallel they were instructed to gradually reduce their daily benzodiazepine usage. Participants ingested the study medication approximately 2 h before bedtime with a small meal.

Main outcome variables

Circadian rest-activity rhythms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200913048705N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **retrospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Elham Hajipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of melatonin on circadian rest-activity rhythms during benzodiazepine tapering in patients with bipolar disorder and comparing it with the control group

Public title
The effect of melatonin on circadian rest-activity rhythms

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 18 years or above Had a diagnosis of bipolar mood disorder based on DSM-5 Were treated with at least one antipsychotic drug and had a daily use of at least one benzodiazepine drug for a minimum of 3 months
Exclusion criteria:
 Present with current violent or aggressive behavior Diagnosed with mental retardation, pervasive developmental disorder, dementia, Physical diseases including hepatic impairment, terminal illness, severe somatic comorbidity, or epilepsy Allergic to any compounds in the study medication Fertile women Breastfeeding women Lack of informed consent Comorbid mental disorders Use of opioids and other drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
The pockets containing medications (melatonin and placebo) were coded, and each code was written on the specific card. Thereafter, eligible patient was assigned to each group, randomly by selecting among shuffling cards. So, allocation sequence was concealed until the moment of assignment, and nobody knows what is the next treatment allocation must be. It should be mentioned that participants, health care providers, assessor and data collector unaware of the assigned intervention (allocated codes).

Blinding (investigator's opinion)
Single blinded

Blinding description
Only participants in this study are blind to whether the drug is melatonin or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Science

Street address

Baharan hospital- Emam Khomeini Ave- Zahedan- Sistan and Baluchestan

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Sistan-va-Balouchestan

Postal code

9819713955

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.ZAUMS.REC.1399.457

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

Circadian rest-activity rhythms

Timepoint

In days one, two and three

Method of measurement

Actigraph

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with bipolar disorder which take melatonin when their usual benzodiazepine dosage was gradually tapered

Category

Treatment - Drugs

2**Description**

Control group: Patients with bipolar disorder which take placebo when their usual benzodiazepine dosage was gradually tapered

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baharan hospital

Full name of responsible person

Dr. Elham hajipour

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Elham hajipour

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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