

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluating the effects of melatonin in improving sleep quality in patients with generalized anxiety disorder or major depressive disorder

Protocol summary

Study aim

Evaluating an effective way to increase the sleep quality in GAD or MDD patients

Design

A clinical trial with a control group, with parallel, double-blind, randomized groups, will be performed on 78 patients. The RNT table was used for randomization.

Settings and conduct

Drug and placebo packages will be coded per random number table and only information about to use the medication and code of the product will be written on the product label. Patient information and information regarding study outcomes will be recorded using the special code and all of this work doing at Tabriz university of medical sciences

Participants/Inclusion and exclusion criteria

1. Patients with a diagnosis of Generalized Anxiety Disorders or Major Depressive Disorders approved by a psychiatrist 2. 18 years or older 3. Groningen Sleep Quality Score more than 6 when medication started 4. Pittsburg Sleep Quality Index more than 5 when medication started

Intervention groups

Patients with a diagnosis of Generalized Anxiety Disorders or Major Depressive Disorders approved by a psychiatrist and supervised at the Razi Hospital Psychiatric Disorders Clinic will be included in the study. At the time of admission, patients' sleep quality was assessed using the Groningen Sleep Quality Score, and patients with a score of 6 or higher, PSQI above 5 will be included in the study. The study will be a randomized double-blind clinical trial with placebo control. The effects of melatonin over 4 weeks in patients with MDD or GAD are assessed using grading scales for depression and sleep quality.

Main outcome variables

Pittsburg Sleep Quality Index Decreases Groningen Sleep Quality Score Decreases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210921052540N1**

Registration date: **2021-11-04, 1400/08/13**

Registration timing: **prospective**

Last update: **2021-11-04, 1400/08/13**

Update count: **0**

Registration date

2021-11-04, 1400/08/13

Registrant information

Name

Sina SeyedImani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3371 0307

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-16, 1400/08/25

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of melatonin in improving sleep quality in patients with generalized anxiety disorder or major depressive disorder

Public title

Melatonin in Depression or Anxiety

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of depression or anxiety by a doctor PSQI score above 5 GSQS score above 6

Exclusion criteria:

PSQI score less than 5 GSQS score less than 6 Patient dissatisfaction

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be carried out using a random number table, the person responsible for patient allocation by RNT-table will be blinded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo packages will be coded per random number table and only information about to use the medication and code of the product will be written on the product label. Patient information and information regarding study outcomes will be recorded using the special code.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

Street address

6th floor, Pharmacotherapy Department, Tabriz University of Medical Sciences Pharmacy Faculty, Attar Neyshabouri st., Tabriz, East Azerbaijan , Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5167747899

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.401

Health conditions studied**1****Description of health condition studied**

Sleep Disorder

ICD-10 code

G47.01

ICD-10 code description

Insomnia due to medical condition

Primary outcomes**1****Description**

Groningen Sleep Quality Score

Timepoint

Base line and after a month

Method of measurement

Questionnaire

2**Description**

Pittsburgh Sleep Quality Index

Timepoint

Base line and after a month

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients with in ths group will receive Melatonin 3mg every night before sleep

Category

Treatment - Drugs

2**Description**

Control group: Patients with in ths group will receive Melatonin 3mg every night before sleep

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Psychiatric disorders of Imam Reza hospital of Tabriz University of Medical Sciences

Full name of responsible person

Sina SeyedImani

Street address

No. 105, 1st Floor, Clinic of Psychiatric disorders of Imam Reza hospital of Tabriz University of Medical Sciences, Golgasht St., Tabriz, East Azarbaijan, Iran

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2

Recruitment center

Name of recruitment center

Sheikh Al-Rais Clinic

Full name of responsible person

Sina SeyedImani

Street address

No. 110, 3rd Floor, Sheikh Al-Rais building, Azadi St., Tabriz, East Azarbaijan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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3rd Floor, Central Building no. 2, Golgasht St., Tabriz,

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Soldouzian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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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

Due to data confidentiality and recording the data using specialize code, personal information of the patient won't be shared, rest of the information may be available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available