Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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seyedimani.s@gmail.com

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 useing a random number table, the person responsible for patient allocation by RNT-table will be bilnded.
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, East Azarbaijan, Iran

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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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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