Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the Efficacy of Melatonin in Sleep Disorders of Sarcoidosis Patients

Protocol summary

Study aim
Determination of melatonin effects in the improvement of sarcoidosis patients with sleep disorders

Design
This study is a randomized, parallel-group, and double-blind. One hundred patients with sarcoidosis and sleep-related disorders are randomly divided into intervention or control groups.

Settings and conduct
Place of study: Dr Masih Daneshvari Hospital How to do the study: One hundred of patients with pulmonary sarcoidosis and sleep-related disorders, are divided randomly into two intervention or control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with age above 18 years with pulmonary sarcoidosis and sleep-related disorders (Pittsburgh Sleep Quality Index equal or greater than 5) that refer to the Sarcoidosis Clinic of Masih Daneshvari Hospital Exclusion criteria: .Pregnancy . Breastfeeding . Neurological disease (stroke, epilepsy, tumor, previously neurologic manipulation) . Use of any sedative or hypnotic drugs (anti histamine drugs, benzodiazepines) . Use of stimulant drugs . Allergy to melatonin or formulation components . Having parasomnia . Shift work sleep disorder . Fluvoxamine consumption

Intervention groups
Patients in the intervention group receive 3 mg melatonin (Razak Pharmaceutical company, Iran) one hour before sleep, for three months. Patients in the control group do not receive melatonin.

Main outcome variables
Sleep quality Daytime sleepiness Quality of life Fatigue status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151227025726N25**
Registration date: **2021-05-19, 1400/02/29**
Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**
Update count: **0**

Registration date
2021-05-19, 1400/02/29

Registrant information

Name
Farzaneh Dastan

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 912 270 5933

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f_dastan@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Efficacy of Melatonin in Sleep Disorders of Sarcoidosis Patients

Public title

The Effects of Melatonin in Sleep Disorders of Sarcoidosis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with age above 18 years with pulmonary sarcoidosis and sleep-related disorders (Pittsburgh Sleep Quality Index equal or greater than 5) that refer to the Sarcoidosis Clinic of Masih Daneshvari Hospital.

Exclusion criteria:

Pregnancy Breastfeeding Neurological disease (stroke, epilepsy, tumor, previously neurologic manipulation) Use of any sedative or hypnotic drugs (anti histamine drugs, benzodiazepines) Use of stimulant drugs Allergy to melatonin or formulation components Having parasomnia Shift work sleep disorder Fluvoxamine consumption

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. Twenty-five blocks including four patients generated with online website (www.sealedenvelope.com/simple-randomiser/v1/lists). In each block, two patients will be assigned to melatonin group and two patients will be assigned to control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Investigator, outcome assessors, and data analyst are blind to the study groups until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Pharmacy and Nursing and Midwifery- Shahid Beheshti University of Medi

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-02-14, 1399/11/26

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.339

Health conditions studied

1

Description of health condition studied

Pulmonary Sarcoidosis

ICD-10 code

D86.0

ICD-10 code description

Sarcoidosis of lung

Primary outcomes

1

Description

The assessment of sleep quality

Timepoint

The assessment of sleep quality at initiation of study and 3 month after melatonin consumption

Method of measurement

With the measurement of PSQI and GSDS questionnaire scores

2

Description

The assessment of daytime sleepiness

Timepoint

The assessment of daytime sleepiness at initiation of study and 3 month after melatonin consumption

Method of measurement

With the measurement of ESS questionnaire score

3

Description

The assessment of fatigue status

Timepoint

The assessment of fatigue status at initiation of study and 3 month after melatonin consumption

Method of measurement

With the measurement of FAS and PROMIS questionnaire scores

4

Description
The assessment of life quality
Timepoint
The assessment of life quality at initiation of study and 3 month after melatonin consumption
Method of measurement
With the measurement of SF-12 questionnaire score

Secondary outcomes

1

Description
The assessment of pulmonary function
Timepoint
The assessment of pulmonary function at initiation of study and 3 month after melatonin consumption
Method of measurement
With the spirometry method

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive melatonin 3 mg for Razak pharmaceutical company, one hour before sleep for one month.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group do not receive melatonin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan
Street address
Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hassan Yazdan Panah
Street address
Shahid Beheshti Faculty of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran
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yazdanpanah@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Faezeh Feizabadi
Position
Resident of Clinical Pharmacy
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
All the potential data can be shared after blinding.
When the data will become available and for how long
Researchers working in academic institutions
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
For research purposes and meta-analysis studies
From where data/document is obtainable
Dr. Farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
What processes are involved for a request to access data/document
Official letter to the researchers through Email (fzh.dastan@gmail.com).
Comments