Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Effects of Melatonin in Improvement of Chronic Fatigue Syndrome and Quality of life in Patients with Pulmonary Sarcoidosis

Protocol summary

Study aim
Determining the effects of melatonin in improvement of chronic fatigue syndrome and quality of life in patients with pulmonary sarcoidosis

Design
A controlled, parallel groups, randomized, single blinded and phase 3 clinical trial on 100 patients. The online site (www.sealedenvelope.com/simple-randomiser/v1/lists) and the randomization block method are used for randomization.

Settings and conduct
Place of study: Masih Daneshvari Hospital. How to do the study: 100 patients are randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People over 18 years of age with pulmonary sarcoidosis and concomitant sleep disorder (PSQI ≥ 3) who refer to the sarcoidosis clinic of Masih Deneshvari Hospital and have also signed the study consent form. Non-inclusion criteria: Patients who are pregnant, lactating, have a history of central nervous system disease, use any sleep-sedating drugs and stimulant drugs, are allergic to melatonin or formulation components, have parasomnias, sleep disorders related to shift work, and fluvoxamine use.

Intervention groups
Patients in the intervention group receive 3 mg of melatonin one hour before going to sleep for three months. In the control group, patients do not use melatonin before going to sleep

Main outcome variables
Average sleeping and waking time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151227025726N32**
Registration date: **2023-05-01, 1402/02/11**
Registration timing: **prospective**

Last update: **2023-05-01, 1402/02/11**
Update count: **0**

Registration date
2023-05-01, 1402/02/11

Registrant information

Name
Farzaneh Dastan

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-20, 1402/02/30

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effects of Melatonin in Improvement of Chronic Fatigue Syndrome and Quality of life in Patients with Pulmonary Sarcoidosis

Public title

Effects of Melatonin in Patients with Pulmonary Sarcoidosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People over 18 years old People with pulmonary sarcoidosis and concomitant sleep disorder (PSQI ≥ 3) Have signed the consent to participate in the study

Exclusion criteria:

Pregnancy Breastfeeding History of central nervous system disease (stroke, epilepsy, tumor, history of neurological manipulation) Taking any sedative-hypnotic drugs (antihistamines, benzodiazepines) Taking stimulant drugs Allergy to melatonin or formulation components Having parasomnias Shift work sleep disorder Taking fluvoxamine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method is used in this study. Twenty-five blocks including 4 patients generated with online website (www.sealedenvelope.com/simple-randomiser/v1/lists). In each block, 2 patients will be assigned to melatonin group and 2 patients will be assigned to control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the main investigator is unaware of the study groups. The randomization form will be provided to the nurse after evaluation of the inclusion and exclusion criteria and administration will be done based on the form. The investigator is blind to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe of Shahid Beheshti University of Medical Sciences

Street address

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

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Province

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Postal code

1983963113

Approval date

2023-01-10, 1401/10/20

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.206

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 amount of sleepiness during the day

Timepoint

At the start and end of the study

Method of measurement

ESS criteria

2

Description

Fatigue state

Timepoint

At the start and end of the study

Method of measurement

FAS and PROMIS criteria

3

Description

Quality of Life

Timepoint

At the start and end of the study

Method of measurement

SF-12 criteria

Secondary outcomes

1

Description

Pulmonary function of patients

Timepoint
At the start and end of the study
Method of measurement
Spirometry

Intervention groups

1

Description
Intervention group: Patients receive 3 mg of melatonin one hour before bedtime for three months.
Category
Treatment - Drugs

2

Description
Control group: Patients do not use melatonin before going to bed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan
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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
Afshin Zarghi
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3rd floor, School of Medicine, Evin St, Shahid Chamran Highway
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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
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
Sahar Yousefian
Position
Hospital pharmacist
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Medical Pharmacy

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Person responsible for updating data

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Latest degree

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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 potential data can be shared after making patients unidentifiable.

When the data will become available and for how long

Six months after publishing the results.

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