

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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)

###### Phone

+98 912 270 5933

###### Email address

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](http://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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1956944413

#### **Phone**

+98 21 2712 3000

#### **Email**

f\_dastan@sbmu.ac.ir

## **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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1991953381

#### **Phone**

+98 21 8820 0080

#### **Email**

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**

Medical doctor

#### **Other areas of specialty/work**

Medical Pharmacy

#### **Street address**

Shahid Beheshti Faculty of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran

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faezehfe@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Dastan  
**Position**  
Assistant Professor, Clinical Pharmacy Specialist  
**Latest degree**  
Specialist  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Faezeh Feizabadi  
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Resident of Clinical Pharmacy  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**

Shahid Beheshti Faculty of Pharmacy, Niayesh  
Highway, Valiasr Ave, Tehran, Iran

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**Postal code**  
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**Phone**  
+98 21 8820 0118  
**Email**  
faezehfe@gmail.com

## 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