

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of melatonin on subjective sleep quality in patients with chronic obstructive pulmonary disease

Protocol summary

Summary

The aim of our study was to evaluate the effect of melatonin tablet on subjective sleep quality in outpatient patients with clinically stable COPD. This randomized, double-blind, placebo-controlled study was done on 54 patients with confirmed moderate to severe COPD who had poor sleep quality (According to the Pittsburgh Sleep Quality Index, PSQI>5). Oxygenation according to pulse oximeter and rate of sleepiness on basis of ESS (Epworth Sleepiness scale) was also measured for all of the patients. None of the participants had a history of disease exacerbation 4 weeks prior to the study, obstructive sleep apnea, mental disorder, hypnotic-sedative medication, nocturnal oxygen therapy and shift work. Patients received 3 mg melatonin (N = 27 or placebo (N = 27), orally in a single dose, 1 h before bedtime for 30 consecutive days. At the end of the study pulmonary function test, pulse oximeter, ESS and PSQI was measured for all of the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110237872N1**

Registration date: **2011-12-30, 1390/10/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-30, 1390/10/09

Registrant information

Name

abolhasan halvani

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and

Health Services

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin on subjective sleep quality in patients with chronic obstructive pulmonary disease

Public title

Effect of melatonin on subjective sleep quality in patients with chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :COPD patients in stage 2-4 according to GOLD criteria with poor sleep quality (sleep quality more than 5 according to Pittsburgh Sleep Quality Index (PSQI)) Exclusion criteria : history of COPD exacerbation during to previous 4 weeks , obstructive sleep apnea, mental disorder, or hypnotic-sedative medication, nocturnal oxygen therapy, and shift work

Age

From **40 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences and Health Services

Street address

yazd, Bahonar square

City

yazd

Postal code

Approval date

2011-05-04, 1390/02/14

Ethics committee reference number

17196

Health conditions studied

1

Description of health condition studied

COPD

ICD-10 code

J44.8

ICD-10 code description

Other specified chronic obstructive pulmonary disease

Primary outcomes

1

Description

sleep quality

Timepoint

at the first of the study and one month after the treatment

Method of measurement

According to the Pittsburgh Sleep Quality Index, PSQI

Secondary outcomes

1

Description

oxygenation

Timepoint

at the first of the study and one month after treatment1 month

Method of measurement

pulse oximeter

2

Description

daily sleepness

Timepoint

at the first of the study and one month after treatment1 month

Method of measurement

on basis of ESS (Epworth Sleepiness scale)

3

Description

pulmonary function test

Timepoint

at the first of the study and one month after treatment1 month

Method of measurement

FEV1 ,FVC,FEV1/FVC and FEF25-75

Intervention groups

1

Description

intervention group: Case group received 3 mg melatonin tablet orally in a single dose, 1 h before bedtime for 30 consecutive days

Category

Treatment - Drugs

2

Description

control group :control group received placebo 1 h before bedtime

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Respiratory Clinic of Shahid Sadoughi Hospital
Full name of responsible person
Abolhasan Halvani
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Web page address

Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
research deputy
Street address
Bahonar Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi University of Medical Sciences and Health Services
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty