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

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)).
Excursion 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

Blinding (investigator's opinion)
Double blinded

Placebo
Used

Assignment
Parallel

Other design features
empty

Secondary Ids

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 treatment
Method of measurement
pulse oximeter

2
Description
daily sleepness
Timepoint
at the first of the study and one month after treatment
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 treatment
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
Street address
City
yazd
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
   Name of organization / entity
      Shahid Sadoughi University of Medical Sciences and Health Services
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      Assistant professor
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   Email
      halvani@ssu.ac.ir
   Web page address

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