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

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))
Excusion 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 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
treatment group :control group received placebo 1 h before bedtime

Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Respiratory Clinic of Shahid Sadughi 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

**Full name of responsible person**
Dr. Abolhasan Halvani

**Position**
assistant professor

**Other areas of specialty/work**

**Street address**
No 7, Adab alley, Kashani Street

**City**
Yazd

**Postal code**
8916784538

**Phone**
+98 35 1623 4986

**Fax**
+98 35 1822 4100

**Email**
halvani@ssu.ac.ir

**Web page address**

Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Shahid Sadoughi University of Medical Sciences and Health Services

**Full name of responsible person**
DR Abolhasan halvani

**Position**
Assistant professor

**Other areas of specialty/work**

**Street address**
No 7, Adab alley, Kashani Street

**City**
yazd

**Postal code**
8916784538

**Phone**
+98 35 1623 4986

**Fax**
+98 35 1822 4100

**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
<table>
<thead>
<tr>
<th>Analytic Code</th>
<th>Data Dictionary</th>
</tr>
</thead>
<tbody>
<tr>
<td>empty</td>
<td>empty</td>
</tr>
</tbody>
</table>