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OPEN PEER REVIEW

Study of the Effects of Melatonin on Sleep Disorders in Pulmonary Sarcoidosis Patients

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

1 comment · 24 Dec 2022

Referee 1 Reviewer

MINOR REVISION 24 Dec 2022

Dear Authors,
This is an interesting study of the effects of melatonin on sleep disorders in pulmonary sarcoidosis patients. Below I have provided my comments.
1- Please state that the consent form was signed by all patients before inclusion.
2- Furthermore, please describe the reason for excluding the patients who were taking fluvoxamine.

2

Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Editor,

On behalf of my co-authors, I submit the responses to the reviewers' comments and the revised manuscript entitled, **"Study of the Effects of Melatonin on Sleep Disorders in Pulmonary Sarcoidosis Patients".** Please find the responses to the reviewers' comments in the next pages. We have addressed all the comments and revised the manuscript accordingly. The revised sections have been highlighted in the text.

We want to thank the reviewers for their important input. We believe their suggested changes have helped to significantly improve the quality of this paper over the previous version.

Thank you for the opportunity to have this work considered for publication in the Journal of Iranian Journal of Pharmaceutical Research. Please do not hesitate to contact me if further revision is needed.

Sincerely,

Comments from Reviewer 1

Number	Comment	Reply

1	Please insert the consent form was signed by all patients before inclusion.	Thanks for your kind comment. We added the consent form to the file's session during submission. The below sentence was added to the methods section of the manuscript before inclusion: "Informed written consent was obtained from all patients before random allocation of the study groups."
2	Please describe the reason for excluding the patients who were taking fluvoxamine.	Thanks for your informative comment. We excluded patients who were taking fluvoxamine, because Concomitant use of melatonin and fluvoxamine (potent CYP450 1A2 inhibitors) are contraindicated. When fluvoxamine and melatonin are taken at the same time, blood levels of melatonin are significantly higher than if the melatonin was taken by itself. The result of this interaction is an increase in melatonin side effects (eg. headache, nausea, and increased drowsiness). Härtter S, Grözinger M, Weigmann H, Röschke J, Hiemke C. Increased bioavailability of oral melatonin after fluvoxamine coadministration. Clin Pharmacol Ther. 2000 Jan;67(1):1-6. doi: 10.1067/mcp.2000.104071. PMID: 10668847.

Comments from Reviewer 2

Number	Comment	Reply
1	Is there any difference between the pathophysiology of fatigue, poor sleep quality and excessive daytime sleepiness in patients with Sarcoidosis that lead to showing the response to melatonin?	Thanks for your comment. We added the below part to the discussion section in this regard: There is no definite information on the exact pathophysiology of fatigue, poor sleep quality, and excessive daytime sleepiness in patients with sarcoidosis. However, some research showed that decreased sleep quality is multifactorial; the respiratory symptoms of pulmonary sarcoidosis, granulomatous inflammation of the upper airway, weight gain induced by corticosteroids consumption, and finally, neurosarcoidosis caused poor sleep quality and excessive daytime sleepiness. Melatonin with immunomodulatory and anti-oxidant features can improve sarcoidosis symptoms and consequently reduce sarcoidosis-related fatigue. Furthermore, in some respiratory studies such as, COPD, chronic pulmonary sleep apnea, and asthma, the use of melatonin can improve sleep parameters such as sleep quality. Based on these evidences, melatonin could affect subjective sleep parameters in pulmonary sarcoidosis patients with sleep problems.
2	In addition, there is no information about other medical diseases. So please add other demographic data such as past medical history, oxygen status, and duration of Sarcoidosis.	Thanks for your comment. We added the past medical history and highlighted it in Table.1. We evaluated and compared both groups in terms of Scadding scale which includes the stage of sarcoidosis based on radiologic findings. This scoring system showed to some extent the severity of the disease which incorporates the oxygen status and duration of sarcoidosis. However, we did not include the oxygen status and duration of sarcoidosis as the limitations of our study.
3	I suggest deleting the Infliximab in table 1 based on no patients who received it.	Thanks for your comment. We removed the Infliximab and highlighted table 1.

2 Revision 1

0 comments

No public comments in this round.