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OPEN PEER REVIEW

Melatonin in the Management of Mood and Sleep Problems Induced by Androgen Deprivation Therapy in Prostate Cancer Patients: A Randomized Double-blinded, Placebo-controlled Clinical Trial

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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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Contents

1 Original submission Negar Mortazavi 2
2 Revision 1 3
Authors' reply to reviewers 4
Reviewer and editor comments 8

1 Original submission

1 comment · 25 Jul 2022

Negar Mortazavi Reviewer

MAJOR REVISION 25 Jul 2022

Dear Author,
Thank you for the opportunity to review your manuscript. I offer the following recommendations for your consideration and major modifications.
1-The review needs English revision. You can find some of my suggested modifications in the attached file. The text still needs some grammatical editing.
2. The title needs revision. It is recommended not to use the term “disorder” and to use “prostate cancer” instead of “prostatic cancer”.
3- Please find my suggested modifications in the attached file.

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 reviewers,

I really appreciate your valuable comments in the manuscript. We corrected the manuscript based on your comments.

Please find the below table for our revisions. We presented the revised manuscript in separated uploaded file.

Also we have highlighted the edited parts according to your comments.

Thank you in advance

Reviewer 1:

Question 1: The most important problem in the conclusion of the manuscript is that although there was no significant difference between the two drug groups, melatonin and placebo, it was concluded that melatonin was effective, while this reduction in anxiety and depression is related to the placebo effects of the drug, not the drug itself. Therefore, the conclusion of this manuscript that melatonin is effective in reducing anxiety and depression is wrong and should be properly discussed.

Response to reviewer;

The discussion and conclusion parts in abstract and other section have been edited again. We completely change the conclusion part as follow:

The results of the study demonstrated that melatonin supplementation (6 mg daily for 4 weeks) can improve sleep problems induced by ADT in patients with prostate cancer in term of the sleep quality indices, especially in the sleep latency, disturbance, and duration domains. Non statistically significant improvement was reported in severity of depression, and anxiety. Unless non-significant excessive daytime sleepiness, no other significant adverse events were reported. All findings should be examined in

large and well-designed studies to confirm the optimal dose and duration of melatonin supplementation.
All related parts have been highlighted specially in page 15-17.

Question 2: The number of abstract words is more than 250.

Response to reviewer;

We reduced the words to 246 now.

Question 3: The names of the authors should be removed from the text of the article and the sources should be referenced only by numbers.

Response to reviewer;

The references were edited again; however, mentioning the name of authors when it comes to describing the previous studies is a very common and there are no special regulations for authors in this era.

Question 4: Is prostate cancer staging included in the study inclusion criteria?

Response to reviewer;

Unfortunately, we don't have the detailed data of cancer staging to add the manuscript; however, as mentioned in inclusion criteria we just enrolled non-metastatic prostate cancer patients who are receiving similar treatment protocol (ADT) in general.

Reviewer 2:

Question 1: The review needs English revision. You can find some of my suggested modification in the attached file. The text still needs some grammatical editing.

Response to reviewer;

We have edited the manuscript grammatically and all changes were done in highlighted format. We have considered all your valuable comments in the manuscript.

Question 2: Title needs revision. it is recommended not to use the term “disorder” and use “prostate cancer” instead of “prostatic cancer”.

Response to reviewer;

We changed the title according to your comment. “Melatonin in the management of Mood and Sleep Problems Induced by Androgen Deprivation Therapy in Prostate Cancer Patients: A Randomized Double-blinded, Placebo-controlled Clinical Trial”

Question 2: Please find my suggested modification in the attached file.

Response to reviewer;

Your valuable comments have been considered and edited in the manuscript. We answer each comment boxes separately. In summary, the word disorder changed to problem, the discussion and conclusion part in both abstract and body have been written again. There were some mistakes in Figure 1 and table 3 which were corrected and the related sentences in the text were matched

now.

For evaluation of daytime sleepiness, we added the extra explanation by introducing Epworth Sleepiness Scale score and the references was added (page 7). Some explanation was added below table 3 for those who take hypnotic drugs. The results in Beck depression part were completely written according to real obtained data.

Please find the highlighted parts and comments boxes.

Kind regards,

Azadeh Moghaddas
Corresponding author
Associate Professor of Clinical Pharmacy

2 Revision 1

0 comments

No public comments in this round.