Reviewer's report

Title: Melatonin analgesia is associated with improvement of the descending endogenous pain-modulating system in fibromyalgia: A phase II, randomized, double-dummy, controlled trial

Version: 2 Date: 6 May 2014

Reviewer: Andrei Pernambuco

Reviewer's report:

Interesting and relevant work. There is a series of carefull around the methodology which increases the reliability of the data. Although I recommend publication of the study, I suggest that some points are reviewed: 1) Abstract – Please, you should show at what times the variables of interest were collected (eg; before, one week after the start, after six weeks, so on). 2) Abstract - Improve the presentation of results, the way it was written did not favor the understanding of the results. 3) Methods - You claim to have used the diagnostic criteria 2010, however, these criteria do not include the count of tender points, but the widespread pain index (WPI), in this case nineteen areas should be tested and not 11 as mentioned in line 230. If you have used the 1990 diagnostic criteria, please explain why. 4) Figure 1 - Needs to be adjusted. What was the “n” of the study (275 patients evaluated, 215 excluded, would remain 60 Figure 62 and find after 63 patients - 21 in each group) are confused. The text contained 63 patients. Please, change the Figure 1. 5) Table 1 - There are mistakes that caused the emergence of characters " # " , please, fix it. 6) Results - Between the lines 299 and 304, about the side effects , it would be possible to check whether the difference between groups was statistically significant? I suggest also that you present these data as a graph or table, as they are important for thinking and clinical decision making. 7 ) Discussion - I suggest adding a discussion of the significant differences in clinical status of participants in the amitriptyline group + melatonin , and if and how this difference could have influenced the results . Clearly , this group had more clinical complications (comorbidities, FIQ and overall pain) which may interfere with its comparative analysis . The following work can help them in dealing with this issue (AP Pernambuco, Schetino LP, Viana RS, LS Carvalho, d' Avila Reis D. The Involvement of melatonin in the clinical status of Patients with fibromyalgia syndrome. Clinical and experimental rheumatology. 2014 ).

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:

No to all.