Reviewer’s report

Title: PrEvention of posttraumatic contractus with Ketotifen 2 (PERK 2) – Protocol for a multicenter randomized clinical trial.

Version: 0 Date: 02 Dec 2019

Reviewer: Spencer Lake

Reviewer's report:

This manuscript describes the established protocol and procedure to execute a clinical trial to evaluate the use of ketotifen fumarate to prevent post-traumatic contracture of the elbow joint. The study is well designed and thoroughly motivated, with appropriate logistical arrangements. The results will be insightful and potentially impactful. I have only a few minor comments and suggestions for the research team.

* I suggest breaking down the exclusion criteria in Appendix 3 by subtopic (listed in lines 45-48 of page 4) to make this list clearer.

* Is there any concern with not closely controlling the analgesic regimens across patients? A recent paper by Salib et al (J Ortho Res Dec 2019) showed that administration of an NSAID (celecoxib) led to increased ROM in a rabbit knee preclinical model. Could variation in analgesic types/doses among patients complicate the interpretation of results if one type of analgesic (e.g., NSAID) has a positive anti-fibrotic effect?

* It appears that there isn't much control over the use of the "standardized home therapy program". Meaning, it seems likely that some patients will be subjected to this type of therapy while others won't at all, or perhaps to only a limited extent. While it is well understood and appreciated that home-based physical therapy is very difficult to replicate across all patients, I wonder about the potential effect this might have on study results?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes
Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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