Reviewer’s report

Title: A Pilot Single Centre, Double Blind, Placebo Controlled, Randomized, Parallel Study of Calmagen® Dermaceutical Cream and Lotion for the Topical Treatment of Tinea and Onychomycosis

Version: 1 Date: 07 Apr 2017

Reviewer: Ignacio García- Doval

Reviewer's report:

This paper describes a RCT of topical Calmagen™ for fungal skin infections.

My main concerns are:

* Given the sample size and mixed patients, the title should call it Pilot RCT

* Patient selection was too restrictive: Positive KOH and fungal culture: Given that these methods have low sensitivity, many patients have been excluded, and regression to the mean can justify a large part of the improvement in the primary outcome (mycological cure).

* Causes of exclusion of nearly 50% of screened patients should be described

* References to previous therapy as toxic (page 4, line 51 and others) should be avoided.

* Efficacy analysis should be ITT: that means that all randomized patients should be analysed, and this is not what authors did (“patients who received the study treatment and had at least one efficacy measurement”): This is a per protocol analysis, not "modified ITT".

* Regarding safety, the most conservative analysis is per protocol (and authors used ITT this time)

* Given the unexpected results and obvious conflict of interest, pictures are mandatory.

* Taking into account the low sample size, all results should include 95% CI (not included in primary outcome or abstract), and these should be stratified by disease (onychomycosis and tinea)

* Safety cannot be concluded form such a small trial. Please avoid wrong claims of safety.

Please check that you comply with all CONSORT checklist.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

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.

No

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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