Author's response to reviews

Title: Cysticlean(R) a highly PAC standardized content in the prevention of recurrent urinary tract infections: an observational, prospective cohort study.

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Author's response to reviews: see over
Dear reviewers,

Attached you can find answers to your comments about the manuscript “Cysticlean® a highly PAC standardized content in the prevention of recurrent urinary tract infections: an observational, prospective cohort study”.

We have made appropriate remarks in the manuscript.

Thank you in advance and best regards,

Dr. Sánchez

1) Reviewer Constantino Leonardo

“This is a prospective study in the use of Cysticlean for recurrent post coital UTI. Unfortunately the small number of the sample and the short follow-up doesn’t support the conclusion of the author. The inclusion criteria of at least two UTI in the last two years seems not to be appropriate to define a recurrent symptomatic postcoital UTI. The antibiotic therapy is not mentioned before starting the therapy with Cysticlean”

We have made appropriate remarks in the manuscript.

2) Reviewer Antonio Cicione

“1. Sexual intercourse is well recognized to be a risk factor for urinary infection. Moreover it is also common having LUTS in women after sexual intercourse.

However, it is hard to clearly define a “post coital urinary infection” because the UTI definition needs presents of urinary symptoms and positive urine culture but there is not in specific literature a detailed definition of “post coital urinary infection” (reporting the time relationship between sexual intercourse and IVU diagnosis). Whereby the number of urinary infection episodes (and not “post coital infection”) is recorded as study outcome in this and other studies. For those reasons, the word “symptomatic post coital” should be removed from title study, in order to better focalize the use of Cys after sexual intercourse to prevent recurrent UTI”

Done

2. In discussion section some study limits should be reported. As first the short sample number and follow up period. However they may be acceptable for a pilot study needs to estimate the sample for follow study. Then using a VAS score is not a standardized method or test to assess QoL. However, this simple way may be accepted after a simple consideration about it in discussion

Done

Discretionary Revision

1. Did authors consider the use of contraception in patients such as intrauterine device condoms or diaphragms? An increased risk for UTI is documented in this circumstance

Done
2. Finally, although the study is not a randomized clinical trial, according to CONSORT statement, a study flow diagram could facilitate reader to understand study design.”

Done.

3) EDITOR

1. After reading through your manuscript, we feel that the quality of written English needs to be improved before the manuscript can be considered further.

Done

Abstract? cut short the background. Methods? epidemiological?, results? clearly mention no. of UTIs in 3 months before treatment, 1st and 2nd 3 months during treatment (no. mean±SD each woman and cumulative no. UTIs)

Done

Introduction? introduction too long and looks like that of a text book chapter. Cut short to relevant details only? i.e incidence and prevalence, antibiotic resistance, introduce cysticlean? including its PAC content.

Done

Methods?

? How do you say it is an epidemiological study

Removed

? Why difference in cysticlean dosage schedule based on frequency of intercourse

Done

? Define RSPCUTI properly? i.e. whether culture mandatory before inclusion, how many UTI per 3 months included

Done

Statistical analysis and results?

? Distribution of data?normal?? then only t test can be applied. Kindly mention details of test used for testing distribution characteristics of continuous variables

? Presentation of results is a bit confusing. Kindly present as follows?
- Number of UTIs per patient? before, at 3 and 6 months after cysticlean
- Number of UTI pooled? before, at 3 and 6 months after cysticlean

Done

Discussion?

Must mention limitations more openly? i.e. no. of patients, length of follow up, potential effect of change in voiding habits? do a post hoc power analysis of your study and suggest number of patients and length of follow up required to get more statistically robust results.
Must mention the pilot nature of the study.

Conclusion
Conclusion needs to be toned down. Too robust conclusion based on a small pilot study.

References
Some references not as per journal style. DOI must accompany all online first citations. Tables and figures duplicating the result-text. Present in either one way.