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OPEN PEER REVIEW

Topical Phenytoin Versus Placebo in the Management of Acute Radiation-Induced Dermatitis in Patients with Breast Cancer: A Double-Blind Randomized Controlled 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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1 Original submission

1 comment · 16 May 2022

Referee 1 Reviewer

REJECT 16 May 2022

Dear Associate Editor,
While this study addresses an issue that may be covered by the International Journal of Cancer Management, the priority score assigned to this work is not sufficient for publication. The following comments are offered to help improve the study for future submissions:
1. No information is given regarding patients' second phase of radiotherapy (i.e., the boost phase) when indicated.
2. The type of randomization is not mentioned.
3. The type of analysis is not mentioned. Was it "intention-to-treat analysis" or "per protocol analysis"?
4. No information is given regarding the sample size calculation.
5. Data presentation requires improvement. This type of clinical trial is expected to report relative risk (RR) to show the clinical significance and a confidence interval plus a P-value to show statistical significance.
6. The Discussion section requires improvement.
7. It is suggested that the tables and figures be prepared per the standard guidelines.

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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 Editor

Many thanks for considering our manuscript for reviewing. We appreciate reviewers' comments. We have applied them in the revised manuscript. In following lines we have answered the referee's comments or questions. However, to facilitate review of the manuscripts, the changes which have been made based on the comments are highlighted as yellow.

Hope all the necessary changes have been applied in the revised manuscript.

Best Regards,

Corresponding author

Reviewer #1	
While this study addresses an issue that may be covered by the International Journal of Cancer Management, the priority score assigned to this work is not sufficient for publication. The following comments are advised to improve the study for further submissions:	
1	***No information is given regarding patients' second phase of radiotherapy (i.e., boost phase) when indicated.***
Answer	Thanks for your point of view. The total dose was 50 Gy to whole breast and 10Gy boost to tumor bed with 2 cm margins. It was added to the manuscript in the line of 82 of the page 3.
2	**Type of randomization is not mentioned**
Answer	Thanks for your comment. The volunteered patients were randomly assigned to two groups. Patients received either phenytoin 1% cream (experimental group) or petrolatum cream (placebo group) in blinded tubes which had simply been given a unique confidential code to each tube by a third party (pharmacist). It was added to the manuscript in the line 64 of the page 3.
3	***Type of analysis is not mentioned. Was it "intention-to-treat analysis" or "per protocol analysis"?***
Answer	It was "intention-to-treat analysis".
4	**No information is given regarding the sample size calculation.**
Answer	Included patients With a confidence level of 95% and a power of 80%, assuming 95% of patients would develop no severe dermatitis (RTOG≥3) in the treatment group and 70% in the placebo group, the number of 32 samples in each group was estimated, and with a 10% probability of sample drop, 35 samples entered in each group. It was added to the manuscript in the line 59 of the page 3.
5	***Data presentation requires improvement. This type of clinical trial is expected to report relative risk (RR) to show the clinical significance and a confidence interval plus P-value to show statistical significance.***
Answer	Thirty four patients in phenytoin group (97.1%) and 28 patients in placebo group (80%) did not developed sever dermatitis (RTOG ≥ 3), RR=1.22 (95% CI: 1.02-1.045, P=0.030). The risk ratio (95% CI) was calculated and p values of less than 0.05 were considered as the statistical significant difference. It was added to the manuscript in the line 105 of the page 4.
6	**The Discussion section requires improvement**.
Answer	Thank you for your comment. It was improved and highlighted in discussion section.

7	***It is suggested to prepare the tables and figures per the standard guidelines.***
Answer	Thanks for your opinion.

2 Revision 1

0 comments

No public comments in this round.