



PEER-REVIEW REPORT

Name of journal: *World Journal of Clinical Oncology*

Manuscript NO: 76438

Title: Clinical relevance of the use of Dentoxol® for oral mucositis induced by radiotherapy: A phase II clinical trial.

Provenance and peer review: Unsolicited Manuscript; Externally peer reviewed

Peer-review model: Single blind

Reviewer's code: 05759455

Position: Peer Reviewer

Academic degree: MD

Professional title: Doctor

Reviewer's Country/Territory: India

Author's Country/Territory: Chile

Manuscript submission date: 2022-03-16

Reviewer chosen by: AI Technique

Reviewer accepted review: 2022-03-21 05:58

Reviewer performed review: 2022-04-01 07:56

Review time: 11 Days and 1 Hour

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input type="checkbox"/> Grade B: Very good <input checked="" type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Language quality	<input type="checkbox"/> Grade A: Priority publishing <input checked="" type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
Conclusion	<input type="checkbox"/> Accept (High priority) <input type="checkbox"/> Accept (General priority) <input type="checkbox"/> Minor revision <input checked="" type="checkbox"/> Major revision <input type="checkbox"/> Rejection
Re-review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No



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Peer-reviewer statements	Peer-Review: [<input checked="" type="checkbox"/>] Anonymous [<input type="checkbox"/>] Onymous Conflicts-of-Interest: [<input type="checkbox"/>] Yes [<input checked="" type="checkbox"/>] No
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SPECIFIC COMMENTS TO AUTHORS

Dear authors Please find reviewer's comments- 1. Keywords need to be arranged alphabetically 2. Mention the study design 3. Sample size estimation should be included 4. references are too old. Kindly add recent references (preferably last two years) 5. et al. should be included after 6 authors. 7. Manuscript needs to be run on grammarly for spell and grammar check



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Peer-review model: Single blind

Reviewer's code: 05989344

Position: Peer Reviewer

Academic degree: DDS, MD, MSc

Professional title: Assistant Professor

Reviewer's Country/Territory: Armenia

Author's Country/Territory: Chile

Manuscript submission date: 2022-03-16

Reviewer chosen by: Dong-Mei Wang

Reviewer accepted review: 2022-06-10 08:27

Reviewer performed review: 2022-06-10 15:27

Review time: 6 Hours

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input type="checkbox"/> Grade B: Very good <input checked="" type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Language quality	<input type="checkbox"/> Grade A: Priority publishing <input checked="" type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
Conclusion	<input type="checkbox"/> Accept (High priority) <input type="checkbox"/> Accept (General priority) <input checked="" type="checkbox"/> Minor revision <input type="checkbox"/> Major revision <input type="checkbox"/> Rejection
Re-review	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No



Peer-reviewer statements	Peer-Review: [<input checked="" type="checkbox"/>] Anonymous [<input type="checkbox"/>] Onymous Conflicts-of-Interest: [<input type="checkbox"/>] Yes [<input checked="" type="checkbox"/>] No
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SPECIFIC COMMENTS TO AUTHORS

A review report of the manuscript titled “Clinical relevance of the use of Dentoxol for oral mucositis induced by radiotherapy: A phase II clinical trial”. Authors aimed to describe the clinical impact of the use of Dentoxol in severe oral mucositis. They concluded that the incorporation of Dentoxol mouth rinse in clinical protocols as a complement to cancer therapy to prevent and/or treat oral mucositis secondary to radiotherapy is justified. There are concerns that should be addressed: 1. In my view Introduction contains some unnecessary information. Introduction should be very specific and not include very general information (for example it is not clear in why authors included information regarding treatment costs; etc...). Authors should provide the background of the study, the scientific gap and based on this they should formulate the study aim. Thus I highly recommend to reduce Introduction keeping only very relevant information. 2. In the Materials and methods section authors should present the statistics information. 3. In the Discussion authors need to present the effectiveness of other medicaments/adhesive films/mouthwashes for the treatment various oral ulcers/mucositis and compare with Dentoxol. I recommend this article: Heboyan A, Avetisyan A, Skallevoid HE, Rokaya D, Marla V, Vardanyan A. Occurrence of Recurrent Aphthous Stomatitis (RAS) as a Rare Oral Manifestation in a Patient with Gilbert's Syndrome. Case Rep Dent. 2021 Apr 16;2021:6648729. doi: 10.1155/2021/6648729. PMID: 33953989; PMCID: PMC8068538.



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Peer-review model: Single blind

Reviewer's code: 05081094

Position: Peer Reviewer

Academic degree: MD

Professional title: Doctor

Reviewer's Country/Territory: United Kingdom

Author's Country/Territory: Chile

Manuscript submission date: 2022-03-16

Reviewer chosen by: Dong-Mei Wang

Reviewer accepted review: 2022-06-14 11:05

Reviewer performed review: 2022-06-14 12:15

Review time: 1 Hour

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input type="checkbox"/> Grade B: Very good <input type="checkbox"/> Grade C: Good <input checked="" type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Language quality	<input type="checkbox"/> Grade A: Priority publishing <input checked="" type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
Conclusion	<input type="checkbox"/> Accept (High priority) <input type="checkbox"/> Accept (General priority) <input type="checkbox"/> Minor revision <input checked="" type="checkbox"/> Major revision <input type="checkbox"/> Rejection
Re-review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No



Peer-reviewer statements	Peer-Review: <input checked="" type="checkbox"/> Anonymous <input type="checkbox"/> Onymous Conflicts-of-Interest: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
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SPECIFIC COMMENTS TO AUTHORS

Dear Authors, Thank you for this small phase 2 study. The authors have made very specific conclusions of "statistical efficacy" of this dentoxol. As usual, this is a very niche subject and there are many alternative agents in the market. 1) there is always a problem of selection bias The patients seem to be randomized to placebo versus treatment- were they blinded to the medication? Could I enquire if the clinicians assessing the mucositis grade were also equally blinded? This agent has list of ingredients "its components (purified water, xylitol, sodium bicarbonate, eugenol, camphor, parachlorophenol and peppermint essence)" that can taste, look, feel the same and it can influence the grading of toxicities. 2) The statistical principle of Bonferroni correction https://en.wikipedia.org/wiki/Bonferroni_correction In the table 1- the authors have given a number of significant calculations. How do we know the significance is not due to repeatedly looking for correlations? The Table 1 and the methodology does not actually say how long is the radiotherapy course if for. The key is the dose and fractionation (plus/minus chemo or cetuximab + location/ volume of disease) will determine the time, duration of mucositis of these patients. Smoking status, alcohol status, p16 status are useful surrogate markers of compliance (heavy smoker, heavy alcohol consumption and p16 -ve status are usually marker of poorer compliance in Squamous cell carcinoma HN patients). I appreciate the hard work of authors but must stress that extensive care and effort must be taken to ensure the validity of said findings. Without understanding the rest of the methodology/ patients/ treatments, it is hard to comment if the conclusions are valid. I certainly hope so as - what is in the placebo? Is it just sterile water? You would hope there is a chance



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of reproducibility with this kind of intervention trials! Please can the authors address these concerns in order to improve reproducibility in clinical practice. BW



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Peer-review model: Single blind

Reviewer's code: 05465473

Position: Peer Reviewer

Academic degree: DDS, MSc, PhD

Professional title: Professor

Reviewer's Country/Territory: Lebanon

Author's Country/Territory: Chile

Manuscript submission date: 2022-03-16

Reviewer chosen by: Dong-Mei Wang

Reviewer accepted review: 2022-06-10 09:19

Reviewer performed review: 2022-06-17 05:28

Review time: 6 Days and 20 Hours

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input checked="" type="checkbox"/> Grade B: Very good <input type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
Language quality	<input checked="" type="checkbox"/> Grade A: Priority publishing <input type="checkbox"/> Grade B: Minor language polishing <input type="checkbox"/> Grade C: A great deal of language polishing <input type="checkbox"/> Grade D: Rejection
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SPECIFIC COMMENTS TO AUTHORS

1. you wrote about mucositis bacterial colonization. Is there any other microorganisms that are able to colonize the lesion? what about candida albicans? 2. In the introduction, a big paragraph about Dentoxol is without any references. 3. For me, the results section in the text can be more elaborated 4. the references used are relatively old. only 3 out 23 references are from the last 5 years. Try to replace and/or add new references



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Peer-review model: Single blind

Reviewer's code: 04135931

Position: Editorial Board

Academic degree: MD

Professional title: Professor

Reviewer's Country/Territory: Turkey

Author's Country/Territory: Chile

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Reviewer chosen by: Dong-Mei Wang

Reviewer accepted review: 2022-06-13 12:55

Reviewer performed review: 2022-06-19 19:44

Review time: 6 Days and 6 Hours

Scientific quality	<input type="checkbox"/> Grade A: Excellent <input type="checkbox"/> Grade B: Very good <input checked="" type="checkbox"/> Grade C: Good <input type="checkbox"/> Grade D: Fair <input type="checkbox"/> Grade E: Do not publish
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SPECIFIC COMMENTS TO AUTHORS

The manuscript entitled "Clinical relevance of the use of Dentoxol for oral mucositis induced by radiotherapy: A phase II clinical trial." Has a title and abstract which reflect and summarize the manuscript. The background of the manuscript is adequately described. The Method of the manuscript is clear. The effect of Dentoxol mouthwash was tested in 55 patients and 53 patients were selected as the control group. The statistics are held properly. As a conclusion the researchers found that the Dentoxol group presented a lower number of patients with severe oral mucositis, with a statistically significant difference at weeks 3 and 4 of follow-up. In the discussion section the manuscript findings are compared and discussed in detail with the literature. Illustrations and tables are understandable and sufficient. Language is fine and statistical method is clear The manuscript has a conclusion that adds knowledge to the literature and has an impact on clinical practice. In my opinion the manuscript is acceptable for publication.