Author’s response to reviews

Title: RESEARCH PROTOCOL: CISPLATIN-ASSOCIATED OTOTOXICITY AMONGST PATIENTS RECEIVING CANCER CHEMOTHERAPY AND THE FEASIBILITY OF AN AUDIOLOGICAL MONITORING PROGRAM

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Comment Amendment

1. Request for funding letter and original ethics approval document The attachments are included herewith. Please note the following:

1. The University of KwaZulu-Natal Biomedical Research Ethics Committee (BREC) approved the study on 11 November 2013 (BE 064/13). (Attachment 1)

2. On 07 July 2014, the BREC approved a change in the title of the study to include cervical cancer patients as well as a change in the research site, since there had been problems relating to equipment access at Inkosi Albert Luthuli Hospital. (Attachment 2). Please note the reference Number – BE 064/13.

3. On 16 October 2015, recertification of the protocol was approved. (Attachment 3).
4. Apart from the PhD scholarship received for Ms J Paken from the South African Medical Research Council (Attachment 4), funding for the study was received from the following institutions:

A. University of KwaZulu-Natal Competitive Research Grant 2014 (Attachment 5)
B. The Oticon Foundation (Attachment 6)

2. Study status:

The protocol must be for a study that is ongoing. An ‘ongoing’ study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at.

The study is currently ongoing. Recruitment of participants has now been completed and data is being captured on patient demographics and hearing loss. Patient follow up during the course of chemotherapy is currently underway.

3. Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles. No publications have emanated from the results of this study as data entry is still underway and analysis and interpretation is yet be to done.

4. Sample size: please expand on the calculations and sample size chosen. Could you numerically indicate the estimates that will be taken into account to cover for the attrition rates? What would be the final sample size with these estimates included? The following additions have been made in the protocol as well:

F tests - ANOVA: Repeated measures, between factors

Analysis: A priori: Compute required sample size

Input:    Effect size f       =   0.25

                        α err prob       =   0.05
Power (1-β err prob) = 0.80
Number of groups = 2
Number of measurements = 5
Corr among rep measures = 0.5

Output: Noncentrality parameter λ = 8.125
Critical F = 3.967
Numerator df = 1.000
Denominator df = 76.000
Total sample size = 78

To account for attrition of 10%, the study intended to recruit 86 participants at the outset or until the desired sample size of 78 was achieved.

5. Could you please confirm whether cisplatin would have been the standard treatment to enroll patients in regardless of the study? Cisplatin is the standard treatment for patients with cervical cancer regardless of the study.

6. Please provide ALL sections listed under the heading Declarations in our Submission guidelines: http://bmchealthservres.biomedcentral.com/submission-guidelines/preparing-your-manuscript/research-article. Please note also that any Declarations sections which are not applicable to your manuscript should still be included with the statement "Not applicable".

Declarations
- Ethics approval and consent to participate
- Consent to publish
- Availability of data and materials
- Competing interests

- Funding

- Authors' Contributions

- Acknowledgements

- Authors' Information

Ethics Approval and consent to participate

The study has received ethical clearance from University of KwaZulu-Natal Biomedical and Research Ethics Committee (BE064/13). All patients meeting the inclusion criteria and willing to participate will be required to sign a consent document after being informed about the nature of the study either verbally, written or both.

Consent to publish

Not applicable

Availability of data and materials

Not applicable as this is a research protocol

Competing interests

The authors declare that they have no competing interests.
Funding

The study is supported by the Medical Research Council of South Africa in terms of the National Health Scholarship Programme provided for this purpose by the National Department of Health.

The study has also received funding from the Oticon Foundation and the University of KwaZulu-Natal Competitive Research Grant.

Author’s Contributions

JP is the project leader and has collected all of the necessary data for the study. VS is the supervisor and CDG the co-supervisor. VS and CDG made conceptual contributions to the protocol and VS provided the required critique of the research methods. All authors approved the final version of the protocol.

Acknowledgments

Not applicable

Author’s information (Optional)