Reviewer's report

**Title:** Study protocol for a randomized, double-blind placebo-controlled trial of a single preoperative steroid dose to treat nausea and vomiting after thyroidectomy: the tPONV study

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**Reviewer:** Avijit Hazra

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Study protocol for a randomized, double-blind placebo-controlled trial of a single preoperative steroid dose to treat nausea and vomiting after thyroidectomy: the tPONV study.

The paper describes the protocol for a placebo-controlled study involving pre-operative administration of a single dose of intravenous (IV) dexamethasone in an effort to control postoperative nausea and vomiting (PONV) following thyroid surgery. The paper is well written and the methodology has been described in adequate details.

However, the following issues, of concern to this reviewer, should be addressed:

Major Compulsory Revisions

1. The drug is being given prophylactically to control PONV. Hence the word ‘prevent’ is preferable to ‘treat’ in the title. Similarly replace ‘treatment benefit’ under aim of the study with ‘preventive benefit’.

2. One recently published study (Song YK, Lee C. Effects of ramosetron and dexamethasone on postoperative nausea, vomiting, pain, and shivering in female patients undergoing thyroid surgery. J Anesth 2013;27:29-34.) suggests that IV 5-HT3 receptor antagonists may be superior to IV dexamethasone in controlling PONV following thyroid surgery. Many other studies suggest that 5-HT3 receptor antagonists have emerged as major options in controlling PONV following various types of surgery. Therefore, even though the role of dexamethasone in controlling PONV following thyroid surgery is not conclusively established, the rationale for conducting this type of study requires additional justification (since people elsewhere may prefer using ondansetron like drugs rather than dexamethasone) which has not been provided. This point should be touched upon in the discussion.

3. According to the standard anesthesia protocol, all patients in this study will be given fentanyl and remifentanil which are synthetic opioids, and like other opioids may induce nausea. Hence, this becomes a source of bias although patients will not be given opioids as postoperative analgesics, unless absolutely required for
rescue. The extent and duration of surgery might be different for different subjects. This is another potential source of bias. Hence, the statements in the abstract that ‘we reduced bias to the greatest extent possible’ and in the background section ‘this setting allows all known biases to be controlled’ require clarification in the discussion. The first part of the discussion highlights the strengths of the study, the latter part should acknowledge these potential limitations.

Minor Essential Revisions

4. Necessity of postoperative opioid administration cannot be an exclusion criterion for trial subject recruitment. Delete this from Table 1.

5. The word ‘blinded’ has been used at several places. Use the word ‘blind’ instead.

6. Insert comma after double-blind in the title.

7. Replace ‘Discussion’ in the abstract with ‘Conclusion’.

8. Clarify the secondary outcome ‘the amount of anesthetic medication required’.

Discretionary Revisions

9. Check with the editor if links to ethics committee approval documents are required. If not, remove them from the paper.

10. In the ethical issues section some statements are redundant e.g. verbal consent alone will not be sufficient for participation. This section may be simplified.

11. The use of a 100 mm Visual Analog Scale for pain assessment is preferable to a 10-point verbal rating scale. However, it is understood that this cannot be altered if the study has already started. Can a justification be provided in the discussion section.

12. Replace ‘verum’ with the more familiar term ‘active drug’.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.