Reviewer's report

Title: P6 acupoint stimulation for prevention of postoperative nausea and vomiting in patients undergoing craniotomy: study protocol for a randomized controlled trial

Version: 1 Date: 27 March 2013

Reviewer: Anna Lee

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The study protocol describes “a single-center, five-arm, randomized controlled trial” of 300 Chinese patients undergoing craniotomy. All groups will receive a single antiemetic dose of ondansetron 8mg before skin closure. Upon regaining consciousness from general anaesthesia, patients will receive one of five interventions:

1. P6 acupuncture bilaterally for 30 min, stimulated every 10 min to keep de qi sensation
2. Sham acupuncture bilaterally for 30 minutes with no stimulation
3. P6 stimulation via TENS electrodes bilaterally for 30 min, with stimulation frequency and intensity set to when de qi sensation is felt.
4. Sham P6 stimulation via TENS electrode bilaterally for 30 min but device is off
5. Usual practice of no non-pharmacological prevention

The outcomes listed are: the incidence of PONV during the first 24 hours, severity of nausea, total rescue metoclopramide dose used and patient satisfaction with PONV management. The main contribution of this study to the existing literature is that invasive and noninvasive methods are directly compared with a standard antiemetic group. The sample size is adequate to answer the study objectives.

Major compulsory revision

1. Abstract Background. You need to include the control in the primary objective statement.
2. Abstract Methods. Trial design should include a descriptor for type of trial (ie. parallel group, cross-over, factorial) and framework (ie. Superiority, equivalence, noninferiority or exploratory).
3. Please include a statement that all groups were given routine ondansetron 8mg before skin closure, and the route of administration of ondansetron.
4. Methods. Design, first paragraph. Delete statements on intervention and outcomes as this is covered in a later section. Move your hypothesis and study objectives to last paragraph of Background and give full details of type and framework of trial (see point #2 above).
5. Methods. Exclusion criteria. Specify which phase of the menstrual cycle is an exclusion criterion and clarify what you mean by “poorly controlled diabetes mellitus, bleeding disorders and serious systemic disease”.

6. Methods. Specify if dexamethasone or droperidol are used in this clinical setting as these are potential confounders to the outcome.

7. Methods. Include a statement about what demographic and clinical data you are collecting that will be included in a table of baseline data in the final report when the study is completed.

8. Methods. Allocation generation. Please state if stratification was used, and list any factors used for stratification.

9. Methods. State who generated the allocation sequence, who will recruit subjects and who will assign patients to the intervention groups.

10. Methods. Outcomes. Please define PONV. Are you reporting incidence of postoperative nausea, incidence of vomiting, or incidence of nausea and/or vomiting?

11. Methods. Outcomes. Please state how you will measure patient’s satisfaction with PONV management. Did you use a valid and reliable questionnaire as patient’s satisfaction is multi-domain specific?

12. Methods. Statistical analysis. Please describe how you will compare patient satisfaction levels between the five intervention groups.

13. Methods. Statistical analysis. Please describe how you will analyze noninvasive versus invasive methods to answer the second objective stated in the Abstract.

Minor essential revision
1. Methods. Design. Insert a subheading “Patient population and setting”.
4. Methods. Sample size. Correct typographically error “β=0.01 (power 90%).
5. Methods. Statistical analysis. “…quantitative data is presented as mean…” should be replaced with “continuous data is presented as mean…”
6. Methods. Statistical analysis. “Chi-square test is used to compare….other qualitative data” should be replaced with “Chi-square test is used to compare….other nominal data.”

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

Quality of written English: Not suitable for publication unless extensively edited

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.