Reviewer's report

Title: Methylene Blue-Assisted Technique for Harvesting Lymph Nodes after Radical Surgery for Gastric cancer: A Prospective Randomized Phase III Study

Version: 2 Date: 13 August 2013

Reviewer: GEORGE Sgourakis

Reviewer's report:

Major Compulsory Revisions

Explanation of rationale, eligibility criteria for participants, settings and locations where the data will be collected, details of the interventions intended for each group and specific objectives and hypotheses have been addressed satisfactorily in the study protocol.

Is there any published study (or evidence) to compare the differences of Surgeons versus Pathologists LN (without methylene blue) harvesting? Should this is not the case; authors must add this third treatment arm in their study.

While authors clearly define primary outcome measure, this is not so clear for secondary outcome measure which might possibly be the “stage migration”. This issue has to be addressed by a separate sample size/power analysis test.

Authors provide the statistical test to determine sample size but this is given in a way that does not take in consideration the confounders/ stratification factors: the type of gastrectomy, extent of lymph node dissection, and surgeon’s experience. Under these circumstances comparisons within each stratification factor will be insufficiently powered. In my opinion this issue has to be addressed with a larger sample size.

Method used to generate the random allocation sequence, including details of stratification is not given. The same is true for the implementation of allocation sequence generation, participant enrollment and assignment to groups.

Statistical methods used to compare groups for primary outcome (e.g. Mann-Whitney, Wilcoxon Signed Ranks e.t.c.) and methods for subgroup analyses and adjusted analyses are not provided in the methods section.

Discretionary Revisions

Though of minor significance, interim analyses and stopping rules must be provided.

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

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests