Reviewer’s report

Title: Comparison of the effectiveness of low pressure pneumoperitoneum with profound muscle relaxation during laparoscopic donor nephrectomy to optimize the quality of recovery during the early post-operative phase: study protocol for a randomized controlled clinical trial

Version: 1 Date: 18 April 2015

Reviewer: Nigel Hall

Reviewer’s report:

This is a protocol for a conceptually simple trial which will nonetheless be challenging to implement. It is certainly ambitious. Overall I think the protocol needs to pay more attention to detail with greater justification for the primary outcome and the way it is used and interpreted in particular. The protocol would also benefit form the inclusion of a clinical trials statistician.

The trial will be of very little interest to the majority of clinicians with the exception of laparoscopic surgeons.

Major Compulsory Revisions

Study protocol: paragraph 4: Why will the surgeon be informed of treatment allocation if the pressure is maximised? This will remove blinding. Will these patients be removed from the trial? How will they be analysed? If they are removed will you increase the sample size to account for this?

Please provide further detailed description of the post-operative treatment protocols - e.g. analgesia and pain assessment protocols, post-operative feeding etc Will these be standardised between groups (they need to be). What are the criteria for discharge?

Statistical analysis: much more detail is required here. How will the stratification criteria be adjusted for in the analysis? I cannot see any justification for a 10 point difference being clinically relevant in the reference given. This is a key point since it is the primary outcome. What does a 10-point difference actually mean for the patient? Why have you chosen post-operative day 1 as being most important? Will you account for gender in the analysis since the QoR-40 values are different for males and females in many studies. Further the SD is different for males and females and is not 15 in either males or females according to reference 14. Statistical input is needed for this trial.

Competing interests: please provide further detail of this relationship and in particular the role of the funder in study design, data collection, analysis and reporting.

Minor Essential Revisions
Background: Paragraph 3: your pilot study (only 1 author involved in pilot study and this protocol) is mentioned as reference 7, yet later on in Methods your pilot is referenced as reference 6 (no joint authors). This requires clarification.

Methods: Will you stratify for age and is there any need to?

Adverse events: please also include monitoring for adverse events to the deep neuromuscular blockade and sugammadex.

Sample size: what about patients who withdraw and those who are unblinded. Will unblinded patinet be included in the analysis. Will the sample size be increased to account for these?

Discretionary Revisions

Methods: exclusion criteria: please define creatinine as upper level of normal. Following sentence 'as' should read 'and'.

Study protocol: paragraph 4: Has the SRS been used by more that 1 previous study? If so please provide detail as further justification for the use of this tool.

Discussion: paragraph 1: consider changing 'optimizes' to 'improves'

**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