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:** 23 April 2015

**Reviewer:** Michael L Nicholson

**Reviewer's report:**

Overall this is a well designed and well written proposal for a single centre RCT. This is an original study. Although the use of low pressure pneumoperitoneum has been studied in other surgical operations, I do not know of any trial work in laparoscopic live donor nephrectomy.

The control group is appropriate. Low pressure pneumoperitoneum (6 mmHg) is being compared to standard pressure pneumoperitoneum (12 mmHg). Both groups will undergo deep neuromuscular block. This is required to facilitate the surgical view obtained during low pressure laparoscopy but it does have potential complications so it is appropriate to include deep neuromuscular blockade in both arms. The efficacy of the neuromuscular blockade is being assessed objectively by standard techniques.

The study investigators will be blinded to the allocation group but I’m not certain that blinding will be easily achieved. The concern is that experienced surgeons are likely to know when a low pressure pneumoperitoneum is being used because the abdominal cavity will be flaccid. Deep neuromuscular blockade may obviate this but further reassurance is needed on this point.

I am not personally familiar with the surgical rating score (SRS) depicted in Table 1 but this seems fairly subjective. It would be more robust if more than one observer scored this aspect. Presumably a poor view due to problems with the laparoscopic camera will be excluded as causes of poor visibility – this should be mentioned.

I wasn’t sure why the surgeon would be unblended if the SRS does not improve to # 3 after increasing the pressure to 12 mmHg. Why not leave the surgeon blinded and allow him to proceed as he feels necessary i.e with conversion to hand assisted or open? Why let him know what the starting pressure was?

The sample size has been informed by a power calculation but the sample is rather small (n=64). The sample size was designed to detect a 10-point difference in the overall score using the quality of recovery 40 (QoR) scale at post-op day 1. The authors state that this difference is clinically relevant and reference a paper by Myles PS et al (ref 14) to support this. I can’t find mention of the relationship between the QoR score and clinical relevance in the quoted paper. This is important because recovery from laparoscopic nephrectomy is
already good and this suggests that a large sample would be required to show a meaningful improvement with low pressure pneumoperitoneum.

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

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

No conflict of interests to declare