Reviewer's report

Title: The effect of Ultrapro or Prolene mesh on postoperative pain and well-being following Totally Extraperitoneal (TEP) endoscopic hernia repair (TULP): Rationale and Design of the study protocol for a randomised controlled trial

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Reviewer: John Norrie

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The effect of Ultrapro or Prolene mesh on postoperative pain and well being following totally extraperitoneal (TEP) endoscopic hernia repair (TULP): rationale and design of the study protocol for a randomised controlled trial

Statistical / methodological review

Discretionary revisions

The authors supply a well written protocol. The design seems rigorous and the statistical methods seem appropriate for the design. There are several minor issues to consider, as follows:

1. The design compares 2 types of mesh – lightweight and heavyweight – within a specific choice of surgical approach (TEP). The primary outcomes are postoperative pain and well being, but there is no mention of effectiveness, apart from recurrences as a secondary endpoint up to 3 years after the outcome. The concern would be twofold:
   a. If the lightweight is shown to be superior to the heavyweight in terms of pain, the heavyweight might be better than the lightweight in terms of recurrence (for TEP), and
   b. That although the trial is designed to compare the two meshes within TEP, how can the design give reassurance that this was the right surgical approach – i.e. as above, the lightweight is better than the heavyweight (all round, in terms of pain and effectiveness) but that possibly the heavyweight would be better for a different non-TEP surgical approach?

2. Describing the trial as double blind is a bit confusing – the authors then subsequently make it clear that the patient and the clinical assessor of outcomes are blinded, but that obviously the surgeon performing the operation cannot be blinded. I would describe that as a single blind with blinded assessment of outcomes, not double blind.

3. Page 2 – the authors state they are undertaking ‘a complete efficacy ... assessment’ – I read this as a pragmatic trial (albeit single centre) and would have expected to see the trial described as estimating effectiveness, not efficacy?

4. On the other hand, there are just 4 surgeons in a single high volume centre, all
of whom are described as being expert. So is this why the authors are describing it as an efficacy and not an effectiveness trial – it is delivered in the hands of expert surgeons, and so despite an inclusive set of patients, the findings may not be easily generalised from this single centre, expert surgeon setting?

5. It would be useful to give more details of the patient characteristics e.g. average age, proportion working etc?

6. Page 5 – the authors state that they give ‘... preliminary results (updated until July 1st, 2011)’ – these are not so much results, as achieved recruitment targets. Although this is informative, it could be confused as being the final recruitment – I would have included a ‘950 target’ version as well / instead of?

7. Page 5 ‘The block size is 8 patients’ – generally, not considered a good idea to broadcast the block size while recruitment is ongoing.

8. Page 5 ‘The patient, investigator and surgeon involved in the follow up’ – what is the difference between the investigator and the surgeon? That is, who is the investigator here?

9. The authors state (Page 7) ‘The type and amount of analgesics used during the first post operative week are kept in a pain diary’ – so in terms of analysis, are the primary comparisons of pain going to be adjusted for analgesic use? Or as a secondary supporting analysis?

10. Page 7 ‘IPQ, BPI, CCS, VAS, SFP, SF-36, EQ-5D’ – spell out what these instruments are?

11. Page 8 – type ‘Severe pain VAS 4-6’ – should be 7-10?