Reviewer’s report

Title: Interventions in randomised controlled trials in surgery: issues to consider during trial design

Version: 1  Date: 8 July 2015

Reviewer: Kurinchi Gurusamy

Reviewer’s report:

- Major Compulsory Revisions
  None

- Minor Essential Revisions
  None

- Discretionary Revisions
  1. Designing surgical interventions within RCTs: Section 2: first paragraph “A recent systematic review examining reporting standards for surgical interventions found that 30% of trials only reported the name of the intervention under investigation and gave no further written detail” might read better as “A recent systematic review examining reporting standards for surgical interventions found that 30% of trials reported only the name of the intervention under investigation and gave no further written detail” to avoid any confusion that only 30% of trials reported the intervention.

  2. Designing surgical interventions within RCTs: Section 2: It will be useful to add that any planned second operations and the interval between the first and second operation should be included in the details of the intervention. For example, elective two-staged liver resection involves two planned operations but the interval may vary between 2 weeks and 6 weeks. Second look laparotomy may be performed at 24 hours, 48 hours, or 72 hours after the initial laparotomy. It is necessary for authors to state clearly this is a planned second operation and also clearly state the interval between the first and second operations.

  3. Designing surgical interventions within RCTs: Section 4: Before stating how the explanatory and pragmatic trial designs differ in terms of standardisation of the intervention, it will be helpful to describe these terms briefly (for example, explanatory trials are designed to investigate the causal relationship between an intervention and physiological process while pragmatic trials are aimed at informing healthcare policy).

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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.