Reviewer's report

Title: Pylorus resection or pylorus preservation in partial pancreatico-duodenectomy - a randomized controlled trial (PROPP study).

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Reviewer: Rakesh Aggarwal

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This manuscript describes the protocol for a randomized blinded comparison of two modifications of pancreatico-duodenectomy, i.e. with pylorus resection or pylorus preservation. The authors need to address the following issues:

a. The comparison is dependent on surgeons following uniform techniques for surgery and post-surgical treatment. Though the manuscript refers to manuals and fixed policies for these, it would be useful for readers to have a weblink to these documents (if possible) or to have these as a supplementary document on journal website, linked to this publication.

b. In the introduction (review of literature), some issue about references 10 and 11 are unclear – were those all prospective or retrospective, were those randomized and at what time points was DGE measured? Why did those studies have DGE much more commonly than the only prospective trial of ppPD and prPD.

c. The introduction section indicates that: ‘... reasonable ... offer significant benefits in the postoperative period ...’. What these benefits were may be stated more explicitly – in DGE, QoL, survival, etc?

d. Most end points are referred to as: ‘within 30 days’. This is unclear. What could be the range of time points at which primary (and secondary) outcomes would be assessed. The flow chart also refers to outcome measurements at 7 and 14 days? What are those?

e. Sample size has been calculated using a large (absolute risk reduction of 20% -- from 32% to 12%). The only RCT till now had a much smaller reduction. Hence it may be preferable to use a more realistic and lower absolute risk reduction for this calculation.

f. Has the trial started? How many centers are involved?

g. Some parts of the discussion are not relevant.

h. The term ‘pylorus preservation’ needs to be defined clearly at the outset. In the manuscript, this is unclear and an uninitiated reader may be confused between conventional PD (where pylorus is not preserved) and prPD (where pylorus is resected).
i. Relatively minor language issues: For some abbreviations that the authors have defined (e.g. DGE), they continue to use the full form subsequently. The term ‘incidence’ has been used repeatedly in place of a much more scientific ‘frequency’ for occurrence of DGE.

Also address the comments in the attachment