Reviewer’s report

Title: Robotic radical antegrade modular pancreatosplenectomy (RAMPS) versus standard retrograde pancreatosplenectomy (SRPS): study protocol for a randomized controlled trial

Version: 0 Date: 11 Dec 2019

Reviewer: Kirsty Loudon

Reviewer's report:

This is the editorial comment

There needs to be editing of the protocol to ensure the protocol is more comprehensive and the corresponding SPIRIT checklist is completed. Unfortunately, there are too many items with N/A in the checklist. This additional information is required to improve this protocol on the use of Robotic radical antegrade modular pancreatosplenectomy (RAMPS) versus standard retrograde pancreatosplenectomy (SRPS) for patients requiring surgery for pancreatic cancer.

SPIRIT checklist - It is not acceptable for Trials journal for the authors leave any items blank or with N/A in the SPIRIT checklist. Further information is required. Please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

As there are no page numbers in the manuscript it was hard to check details in the SPIRIT checklist. However, there appear to be inconsistencies in the page references in the SPIRIT checklist. Many of the items could not be found on the pages indicated while other items have not been referenced.

Item 2b: All items from the World Health Organization Trial Registration Data Set. Please state: Please refer to Item 2a and registration in the Chinese Clinical Trial Registry, ID: ChiCTR1900020833.

Item 5b: I could not find the details of the sponsor in the protocol and not on page 1, please enter as well as contact details.

Item 5c: role of sponsors etc information needs to be inserted into the protocol. An example of what has been written is: "The sponsor played no part in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication"

Item 5d: This cannot be N/A. Perhaps you could give information on the composition, roles and responsibilities of the coordinating centre and trial steering committee and all groups providing day to day support for the trial. We also need information on who is responsible for all aspects of local organisation including identifying potential recruits and taking consent. Who is supervising the trial and how often they will meet, plus information on the Trial Steering Committee (TSC), and how often they will meet over the course of the trial to oversee conduct and progress. Plus, information and how often the Stakeholder and Public Involvement Group (SPIG) if there is one, and their specific role.

Item 6b: please insert page number for the explanation for the choice of the two comparators in the RCT. In particular there are no references for the choice of Robotic standard retrograde pancreatosplenectomy.
Item 11c: Please state in the SPIRIT checklist that Adherence is not an issue for patients as this is a surgical trial and indicate if there is monitoring of surgeons to check procedures.

Item 11d: relevant concomitant care field needs completing and ensure information in the protocol. Perhaps you could state that Implementing X or X will not require alteration to usual care pathways (including use of any medication) and these will continue for both trial arms

Item 13: time schedule figure is Table 2: Flow chart of the trial.
Item 19: Please give details of plans for data entry, coding, security, and storage, including any related processes to promote data quality etc So for instance will paper based and electronic data entry be used? It appears this is on page 9/35 under Data collection and statistics.

Item 20a: Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analyses plan can be found, if not in the protocol.

Item 20b: please complete methods for any subgroup analysis, if not please state this.

Item 20c: please complete: Analysis needs completion - how will missing data be handled? How will you analyse those that are randomised to the intervention but do not adhere to the intervention? Edit the protocol and put in page number in SPIRIT checklist.

Item 21-23 Monitoring cannot be N/A please insert this information and edit the SPIRIT checklist.

Item 21b please state why N/A re interim analyses and why there is not anticipated to be no formal stopping rules for the trial.

Item 22: Please insert information on reporting of Adverse events (AEs) or Serious Adverse Events (SAEs) and harms from the intervention. It may be that evidence suggests that SAEs are not anticipated so please state this and indicate what potential minor AEs may be anticipated. And that they will be reported to the DMEC and relevant regulatory bodies as required indicating expectedness, serious-ness, severity, and causality.

Item 23: Frequency and plans for auditing trial conduct - needs information, this cannot be N/A. For instance, how often Project Management Group meet to review trial conduct. The Trial Steering Group and the independent Data Monitoring and Ethics Committee meet to review conduct throughout the trial period.

Item 25: protocol amendments - please details plans for notifying of any changes to the protocol i.e. notifying sponsor and funder first then the PI will notify the centres and that a copy of the revised protocol will be sent to the PI to add to the Investigator Site File. You may also want to state that any deviations from the Protocol will be fully documented using a breach report form. You can also include you will update the protocol in the clinical trial registry.

Consent (item 26) and Confidentiality (item 27) cannot be N/A so please complete. Plus, all other N/A.

Item 26a: It was unclear who was actually recruiting the patient? The trial coordinator, surgeon? When is this done?

Item 26b: Can suggest something like this "On the consent form, participants will be asked if they agree to use of their data should they choose to withdraw from the trial. Participants will also be asked
for permission for the research team to share relevant data with people from the Universities taking part in the research or from regulatory authorities, where relevant."

Item 27: Perhaps you could state how you will store information to ensure confidentiality. Verify that data collected during the course of the research will be kept strictly confidential and only accessed by members of the trial team (or individuals from the Sponsor organisation or centre sites where relevant to the trial). Will participants be allocated an individual trial identification number and will participant's details will be stored on a secure database? Who will access rights to the data set? Will anonymised trial data be shared with other researchers to enable international prospective meta-analyses? There appears to be some information under "Data collection and statistics on page 10.

Item 29: This appears to be in the protocol on page 14.

Item 30: Provisions for post-trial care - you could state "There is no anticipated harm and compensation for trial participation" and it would be helpful to know if there will be any provision for post-trial care.

Item 31a: This item is blank in the SPIRIT checklist and there does not appear to be information in the manuscript. Please document dissemination in the protocol and in the checklist. Perhaps you could state how results will be communicated to X and X and other relevant groups via publications, reporting results in databases, data sharing arrangements, twitter - social media or through the sponsor etc

Item 31b: page 15 you state the author contributions please insert page number into checklist or you could also state "All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication." Or All authors have contributed to writing the manuscript as detailed p15, no professional writers have been involved.

Item 31 c: Access to data cannot be N/A - it is really important so complete information. It looks like this information is included on page 14.

Item 32: This item is referred to in Item 26a and cannot be left blank. Where can the reader obtain the Informed consent form. If not in appendix then please state where it can be obtained or perhaps state "These are available from the corresponding author on request." This information is not on page 26

Item 33: See above 26b there will be no biological specimens collected

References: There were 3 articles that could not be checked, please check format for websites, include date checked and ensure sufficient information as in guidelines below. Four articles were not validated (https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol/#references).
**Level of interest**  
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

**Quality of written English**  
Please indicate the quality of language in the manuscript:

Acceptable

**Quality of figures**

All images and figures within the manuscript should be genuine i.e. without evidence of manipulation. No specific feature within an image may be enhanced, obscured, moved, removed, or introduced. If you have concerns about the veracity of the figures you should choose the first option below.

**Statistical review**

Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

**Declaration of competing interests**

Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

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5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.
I declare that I have no competing interests.

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Were you mentored through this peer review?

No