Reviewer's report

Title: Functional outcome of total knee replacement: a study protocol for a prospective, double-blinded, parallel-group randomized, clinical controlled trial of novel, personalized and conventional implants

Version: 1 Date: 16 Aug 2019

Reviewer: Xinhua Qu

Reviewer's report:

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Comments to the Author:

This protocol described a scientific design of a double-blinded RCT for evaluating the functional outcome and patient satisfaction levels after receiving TKA with three types of bearing with a novel design and two additional conventional design. This work will be beneficial to fill the void of the functional evaluation to this new-designed implant, which may guide the surgeons to select the most proper implants to a patient. The design of this RCT have been fully considered and discussed by the researchers, but there still are some points requiring further detailed.

1) The primary outcome measures are mostly based on self-administered PROMs. Although the patient satisfaction levels are an important and primary part of this protocol, the absence of a professional measure from medical staffs may lead to lose of some professional informations on the functional outcomes. Whether a professional objective examination or evaluation should be added to the pre- or post-operative measures needs further consideration. By the way, if the objective functional examinations are needed, whether the training for the sanitation workers are needed, who are the primary researchers during the follow-up trials?

2) The protocol only mentioned that this is a single-centre trial to avoid potential interests relationship in different centres. Actually, many countries have offered many criterias for diagnosis it is known that the surgical skill of the surgeons will lead to different outcomes, so if the surgeons who participate for performing the surgery should be confirmed and recorded as well. If the samples are enough, it could be better to only include the patients receiving the surgery from a same team of surgeons.

3) Page 12 Line 28-29. Individual surgeon's preferences should be detailed. A unified procedure of the surgery should be defined in a RCT of which the potential bias should be avoided. A systematic training maybe helpful before the trial begin.
4) The blinded methods based primarily on an envelope methods, which have plenty of potential risk factors which may lead to unblinded and also easily to be interfered by artificial factors. A more scientific blinded procedure could be better, especially during the grouping procedure, which is connected to the practice of randomised grouping directly, as the surgeon who preforms the surgeries is hardly keep blinded during the surgery procedure finished.

5) Considering the probably loss rate to follow-up, no matter what the reasons are, whether the sample size should be enlarged a little for eliminating this probable bia?

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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

Acceptable

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