Reviewer’s report

Title: Central coordination as an alternative for per patient payment in a multicenter randomized controlled trial: the FAITH trial experience

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Reviewer: Volker Alt

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Review

Central coordination as an alternative for per patient payment in a multicenter randomized controlled trial: the FAITH trial experience

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Trials

The work addresses the interesting and relevant topic of two different management coordination types of RCTs in orthopaedic trauma surgery. The authors compare a central coordinator approach vs. local study coordination at each site.

Overall, the manuscript is of scientific interest and adds value for further planning of RCTs in orthopaedic surgery. Therefore, I recommend acceptance of the paper after minor revision.

Minor Essential Revisions:

One problem of the work is that there is another confounding variable which is the different distribution of hospital types. There is a tremendous difference in the number (percentage) of non-university teaching hospitals in the NL compared to Canada but also compared to the US. So the differences in the outcome may not only be attributable to the different management types of the study coordination but also to this difference in hospital types distribution. Is the higher percentage of non-university teaching hospitals part of the “central study coordination” design or was this just by coincidence? The authors should therefore more focus in the discussion whether or not this combination of central study coordination and high percentage on this issue. E.g. would a central study coordination design in the NL with a high percentage of university hospitals – such as in the US or Canada – would have led to the same results or not? Can the results of the current with faster enrolment of patients and higher inclusion rates be generalized?

The major weakness of the study is that the study design for this research question is limited. The better study of this work would have been if the two models – central management vs. local site management – would have been
conducted in each of the countries as this would have delivered more comparable data which would have been independent from country-specific preconditions and different distribution of hospital types. This limitation should definitely be addressed in the discussion section.

Materials & methods section:
Study characteristics: the time points for enrolment of patients should be considered as results and therefore be presented in the results section.

Conclusion:
The conclusion should be altered and contain practical recommendations for the reader for the set-up of future clinical trials. It should be stated for the reader under which preconditions of the study (depending on the geographical distribution of the participating sites, difficulties in informed consent approval etc.) central coordination or local management with per case payment should be preferred.

**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:**
There is no conflict of interest for me to review this manuscript.