Author’s response to reviews

Title: Routine versus on demand removal of the syndesmotic screw; a protocol for an international randomised controlled trial (RODEO-trial)

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Author’s response to reviews:

Dear dr. Mockridge,

In response to the email we have received on Monday 18th of September 2017, we hereby submit the revised version of our manuscript. The following changes have been made in the study protocol, taking the editorial points into account:

1. Abstract: the date of trial registration has been added to the paragraph trial registration, page 3, line 2
2. Title: the word “protocol” has been added to the title, page 1, line 3
3. The email addresses of all authors have been added to the title page, page 1 line 10-38
4. Methods: the names of all of the sites at which the study will be undertaken are now listed in table 1, page 4-5, line 5 of the paragraph Design.
5. Discussion: a discussion piece is now included on page 11-12, starting at line 10 of page 11
6. A statement has been included to indicate that the subjects have provided informed consent, page 12, line 15-16
7. Author contributions: The initials of all authors have been added to the author contribution paragraph and their role in the manuscript has been stated, page 13, line 7
8. Acknowledgements: all funding information is removed from the acknowledgements section and placed in the Funding section. The acknowledgement section now states: Not applicable.

The earlier received, revised version contains the following changes:
1. Title page: The addition of an author (page 1, line 7) and a participating centre (page 5, table 1, row 7)

2. Abstract: Addition of a missing word and clarification of a sentence (page 2, line 20)

3. Background: addition of a United States incidence rate/reference (page 3, line 7)

4. Inclusion criteria: clarification of inclusion criteria by stating that one or two syndesmotic screws can be placed (page 5, line 5)

5. Statistical analysis: addition of the sentence explaining that secondary outcome measures costs/health care consumption will only be measured in the Netherlands (page 10, line 8-10)

Kind regards,

F. Sanders