Author's response to reviews

Title: Cemented versus non-cemented hemiarthroplasty of the hip as a treatment for a displaced femoral neck fracture - Design of a randomised controlled trial

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Author's response to reviews: see over

Dear Editor,

Re: “Cemented versus non-cemented hemiarthroplasty of the hip as a treatment for a displaced femoral neck fracture – Design of a randomised controlled trial".
Thank you for your positive response of our manuscript.
We have carefully considered the comments from the reviewer, and changed the manuscript accordingly. The changes in our manuscript are highlighted using bold text.

On behalf of all authors;
Sincerely yours,

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Comments to the reviewer's report:

1. Overall comments:

“However, for a strict clinical trial plan, the following study members should be well described,”

These are mentioned in the official protocol as approved by the Medical Ethical Committee. In our opinion they don’t need to be mentioned in the manuscript itself to preserve it’s readability.

“I personally strongly recommended that the protocol can be written according to the following orders. All the necessary information should be provided as clearly as possible”

The recommended orders are used in the official protocol as approved by the Medical Ethical Committee. However, for the manuscript we applied the lay-out used in other research protocols already published in BMC Musculoskeletal Disorders.

Specific comments:

Study design:
"This is a single blinded study theoretically, but the prostheses are different. I am afraid it’s not easy to keep patients blinded. I’d rather believe it’s an open label study. I think it’s more important to arrange a blinded evaluators"

The study is designed and carried out as a single blinded study; the patient is not informed about the type of prosthesis that is used during the whole period of follow up.

In this multi centre trial it’s impossible to arrange blinded evaluators for all the centres, however the SF-12 and GARS are being filled in by the patient and
thereby objectively obtained.

Study population:
“.... suited for treatment with a hemiarthroplasty...is unclear.
Definition of femoral fractures? Similarly, all other variables need a clear definition.”

We added “Garden classification III or IV” to displaced femoral neck fracture and removed and suited “for treatment with a hemiarthroplasty” in the manuscript.

Intervention:
"The prosthesis had better be the same to eliminate the possible differences."

Both prosthesis have good results in the Netherlands and are widely used.
We believe that the current concepts of cemented and non-cemented slightly differ. So we disagree with the referent about this point and see no value in using the same prosthesis both cemented and non-cemented.

Study variables:
"Please address all the variables more clearly. For example, Timed-Up-and-Go (TUG) score and the Groningen Activity Restriction Scale (GARS) are not commonly used. Can use VAS pain score?"

For the evaluation of functioning of this kind of population there is no golden standard of scoring.
We believe the GARS score to be a very useful score as it score for all basic activities like eating, getting dressed etc. The GARS is decribed in the article we refer to in the manuscript.
The TUG score is a validated score to asses the risk of falling and is mentioned in study books on functional testing.
The VAS score is used during the clinical period of the study to measure the effect of the pain-medication as for all our patients.
For the outpatient part of the trial we chose to use an ordinal scale instead of a VAS score.

Follow up:
"How many visits are scheduled? A timetable is recommended.
One year is not long enough."

Assessments at 6, 12 and 52 weeks, as mentioned in the manuscript.

In our opinion 1 year follow up is sufficient as the 1 year mortality rate in this population is 25%. From our own retrospective studies we know that the 2 year mortality is up to 35%.
These mortality rates together with the fact that this very old patient population has many problems to visit the hospital for further follow up make longer follow up of no further contribution to our opinion due to the high mortality rate and the expected drop-outs.

Sample size:
"Please provide the reference of the calculation in mid-thigh pan. It's not clear."

This power analysis is based on the method described in the book of Schouten. Clinical Statistics.[Klinische Statistiek ISBN 9031329789] Chapter 11

Complications (risks)
"Please name them one by one clearly. Is an interim analysis needed? Is there any plan of early termination?"

We changed this in the manuscript; we register the complications by the modified Elixhauser model, as mentioned in the article of Parvizi, JBJS 2007, which reference we added.

There is no interim analysis anticipated based on prior studies on this topic with very small differences between both groups. Furthermore both prostheses are well documented and widely used. Therefore it is not believed that premature study termination based on interim analysis is an issue.

Statistics:
"Survival analysis may be helpful."

This will be done in final analysis.