Dear Editor,

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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Version: 3 Date: 25 March 2009

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Version: 1 Date: 25 March 2009

Author's response to reviews: see over
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 red bold text.

On behalf of all authors;
Sincerely yours,

AJH Vochteloo MD

Comments to the reviewer's report:

“Although the authors insist their own way presenting their study personnel, member of data and safety monitoring board is lacking. This is an important committee monitoring the correct conduction of the trial. Please specify.”

The study will be monitored by the authors AV and PP.
Safety reports are made to the Medical Ethical Committee.
This is added to the manuscript

“I still think this should be an open label study, because the patients may easily know what kind of implants are used on the X-ray, especially when they clearly know two different implants are to be used in the consent form.”

We changed the description to “randomised controlled trial” in the manuscript.

“We still think a blinded evaluator is necessary, because the patient may know his treatment method. We suggest a third-party evaluator who examine the patients without seeing the X-ray or knowing about the treatment method”

We agree with the referent that a blinded evaluator would be a good idea. However, If this study would have been a single center study we might be able to arrange a blind evaluator., but due to logistical reasons, it is impossible to find a third party evaluator to examine all patients in all centres. We don’t have the funding and organisation to pull this off.

Further, the primary outcome measures are scored by the patient himself (they fill in the question forms regarding pain, function scores) or are absolute variables (operating time, complications). Hence there is very little to no bias.


The reference has been added to the manuscript.
“We all know that the follow-up rate of joint replacement had better be at least 5 years. Although the mortality rate in this kind of patients is high, 2-year follow up may detect some more interesting differences, like loosening or protrusion rate, etc”.

Our primary outcome measures are met with a follow up of 1 year.
Radiological outcome is a secondary outcome measure.
We believe that protrusion and loosening will not occur more in 2 years than in 1 year in this quite low demanding group of patients. Detecting a possible difference in protrusion of loosening requires a follow up of 5 years and more. Most patients in this population will not survive this follow up. Furthermore in routine daily care these patients are usually discharged from follow within a year considering the impact of out-patient visits. High 1-year mortality combined with the logistical reasons give very limited follow-up at two years.

“Please add the method of survival analysis to the statistics of the protocol”
Kaplan-Meijer survival analysis. Endpoints are failure/reoperation and mortality.
This has been added to the manuscript

“The prosthesis had better be the same to eliminate the possible differences. It has been postulated that unipolar head tends to cause more acetabular protrusion than bipolar head. I don’t know whether the head design of these two prostheses is similar or else?
I suggest the details of the prostheses should be described.”
Both prostheses have a unipolar head. This has been added to the manuscript after the description of the stems.