Reviewer's report

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

Version: 1 Date: 21 January 2009

Reviewer: Ching-Chuan Jiang

Reviewer's report:

Overall comments:

The present study protocol is to compare the treatment outcome between cemented and cementless hemiarthroplasty for femoral neck fractures in aged patients. There has still a big controversy for this issue. The study goal is good and background information is OK.

However, for a strict clinical trial plan, the following study members should be well described:
- Steering committee:
- Study coordinator:
- Study statistician:
- Study administrators:
- Data and safety monitoring board:
- Contract Research Organization (if necessary):

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.

1. BACKGROUND AND STUDY RATIONALE
2. PATIENT SELECTION
   2.1 Inclusion criteria
   2.2 Exclusion criteria
   2.3 Patient selection process
3. STUDY DESIGN
   3.1 Treatment assignment
   3.2 Operation procedure
      3.2.1 Device
      3.2.2 Implantation procedure
   3.3 Longitudinal follow-up investigations
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.

Study population:
“…. suited for treatment with a hemiarthroplasty…is unclear.

Definition of femoral fractures? Similarly, all other variables need a clear definition.

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

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?

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

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

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

Statistics:
Survival analysis may be helpful.

**Level of interest:** An article of importance in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
'I declare that I have no competing interests'