Reviewer's report

Title: Effectiveness of oral nutritional supplementation for older women after a fracture: a randomized controlled pilot study

Version: 2 Date: 22 July 2010

Reviewer: Maria Teresa Vidán

Reviewer's report:

The authors present an article describing the methods and the problems they found on the performance of an unfinished, randomized controlled study regarding the effectiveness of oral supplementation on older women after a fracture. They also present the preliminary results of a very small sample of patients in the pilot phase of the study.

The subject of the study is important because even if some guidelines recommend the use of nutritional supplements after hip fracture, the evidence of the benefit is very weak so well-designed, randomized trials are necessary.

The strengths of this study are that it is a randomized trial and that it includes nutritional and functional data during follow-up.

Nevertheless, there are some limitations that should be addressed before publication:

- 1.- The title should be changed to: “Effectiveness of Oral Nutritional Supplementation for Older Women after a Fracture: Rationale, Design and Study of the Feasibility of a Randomized Controlled Study” and focus the interest of the article on the description of methods and study development with the inclusion of some results from the pilot phase and exclude a comparative analysis. The final results and conclusions in the whole population should be presented in a future paper.

Major revisions recommended:

- 2.- The authors should describe, or represent in a flow-chart, the number of patients >70 years of age admitted to the hospital with a fracture during the study period, % that were approached, % with the inclusion criteria and % that were finally included. Such data would help evaluating the feasibility of the study.

- 3.- The definition of the timing of baseline albumin determination is key, as is the criterion used to define malnutritional status. At least, whether the determination was performed before surgery must be stated. (It is known that serum albumin concentration change with inflammatory situations and surgery.)

- 4.- It is important to describe how the control of the intervention is done and present the data of adherence they have so far:

  o % of patients that took the complete nutritional supplement every day during admission and how many refer to have done it after discharge
o % of patients that did it without decreasing the usual daily intake.

- Quantity of milk that patients in the control group received and % of patients that had it every day during admission.

These data allow evaluating if a good compliance of this intervention is feasible.

- 5.- The principal end-point must be defined. Which is the operative definition for effectiveness? What is the change in serum albumin determination and when in the follow-up do they consider the intervention to have a nutritional benefit? What is the change in Barthel index during follow-up that they consider relevant and what difference between the groups they hypothesize is considered to be a positive result due to the intervention? Subsequently, they have to estimate the sample size needed to find these differences between groups.

- 6.- They should also explain if the rehabilitation process is the same in both groups.

- 7.- Conclusions should be changed. The current results in this phase of the study and with this small sample do not allow to draw any conclusion about the effect of nutritional supplementation after a fracture.

Discretionary changes:

8.- - To present only descriptive results (table 2) adapted to the definition of outcomes and without comparative analysis. This small sample does not permit to correctly compare the groups adjusting for main confounders.

9.- They should discuss the reasons for the long inclusion period in the pilot phase for such a small sample of participants, and whether they think that these reasons could possibly question the feasibility of the trial.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests