Reviewer’s report

Title: No significant effect on bone mineral density by high doses of vitamin D3 given to overweight subjects for one year

Version: 1 Date: 26 October 2009

Reviewer: Gunnar Sigurdsson

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Minor Essential Revisions:
The main aim of the study was to address the issue of skeletal effects of high dose vitamin D supplements especially the possible negative effect of such a dose on bone as well as a positive one. Given the focus on the need for higher doses of vitamin D these days this is an important research question. However, as the authors point out in this study the effect of vitamin D on bone mineral density, serum OPG and Rankl were only secondary endpoints as the main aim was to study the effect on body weight

Methods and study groups:
As the main aim was to study the effect on weight loss the study group includes only men and women with BMI between 28-47 kg/m2. The age range was 21-70 years of age and the group was recruited by advertisement in local newspapers and from their outpatient clinic. The study consort diagram is well described in Figure 1. Table 1 shows that men were 37% of the study group and mean age of the study group was 47 years. Apart from that, there is no description of the age distribution especially how many women were postmenopausal. The number in the three subgroups, two with vitamin D supplements and one with placebo was around 100 in each group, and this number of course limits the possibility considerably of dividing the cohort into further subgroups. However, the positive effect of vitamin D might be to reduce age related bone loss which may be difficult to verify by such a short follow-up time of one year except in early postmenopausal women. It should therefore be of interest to describe the age distribution in further detail.

The distribution of serum 25-OH-D should be described in more detail. Was the increment in S-25-OH-D dependent on baseline value?

Measurement:
BMD was determined by DXA scans but coefficient of variation is not mentioned. The same applies to the assay for Rankl and OPG, CEV should be mentioned.

Statistical analyses:
No power analysis seems to have been done with regard to the number needed into the study to verify possible changes in the BMD, Rankl and OPG. This may be a reflection of the fact that those variables were only secondary endpoints in
This study.

It should be of interest to see if there were any individuals with increments/decrements in those variables outside the least significant change (2.8xCV) after one year of follow-up.

Results:
Similar numbers of dropouts were observed in the three study groups and the reasons for dropouts should be mentioned.

Conclusions:
The authors point out several limitations in their study and that the results should be evaluated with caution.
Generally with those limitations in mind the manuscript is clearly written.

**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.