Author's response to reviews

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

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Author's response to reviews: see over
Dear Sir,

Concerning manuscript MS: 7353579533057361 "No significant effect on bone mineral density by high doses of vitamin D3 given to overweight subjects for one year" Rolf Jorde, Monica Sneve, Peter A Torjesen, Yngve Figenschau, John-Bjarne Hansen and Guri Grimnes

Thank you for your e-mail from November 27, 2009 with valuable comments from the reviewer. We have the following responses to the Reviewer’s report:

- 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.

OUR RESPONSE: The number of postmenopausal women is now stated on page 8, line 5, and we have included the age distribution in the males and females in Figure 2.

- 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.

OUR RESPONSE: We have now analyzed the postmenopausal women separately, but that did not disclose any statistically significant differences between the 3 groups (page 9, last paragraph).

- The distribution of serum 25-OH-D should be described in more detail.

OUR RESPONSE: We have now included the distribution of serum 25(OH)D as a separate figure (Figure 3).
- Was the increment in S-25-OH-D dependent on baseline value?

OUR RESPONSE: Yes, the increase was highest in those with the lowest 25(OH)D values at baseline, but still there was a significant correlation between baseline and 12 months serum 25(OH)D levels. This is now included on page 9, line 4.

- 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.

OUR RESPONSE: The CVs for the DEXA scans, Rankl and OPG are now included in the Methods section on page 6, lines 7, 8, and 10.

- 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.

OUR RESPONSE: The power calculation was performed regarding weight loss. This is now included on page 7, third paragraph.

- 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.

OUR RESPONSE: That was only the case for two subjects for L2-L4 BMD, which is now included on page 9, third paragraph.

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

OUR RESPONSE: This has previously been described in detail in the paper concerning weight reduction. However, most dropouts did not state a specific reason for leaving the study. This is now stated on page 8, line 6 from bottom.
With these changes we hope the manuscript is suitable for publication in Nutrition Journal.

Yours sincerely

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