Author's response to reviews

Title: Changes in the serum vitamin D and PTH values using denosumab with or without bisphosphonate pre-treatment in osteoporotic patients: A short-term study

Authors:

Yukio Nakamura (yxn14@aol.jp)
Mikio Kamimura (mikamimura@hotmail.com)
Shota Ikegami (sh.ikegami@gmail.com)
Keijiro Mukaiyama (kmuka326@yahoo.co.jp)
Shigeharu Uchiyama (sigeuti@shinshu-u.ac.jp)
Hiroyuki Kato (hirokato@shinshu-u.ac.jp)

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

We submit our manuscript entitled “Changes in the serum vitamin D and PTH values using denosumab with or without bisphosphonate pre-treatment in osteoporotic patients: A short-term study” as a research article to BMC Endocrine Disorders.

Denosumab is a fully human monoclonal antibody that inhibits receptor activator of nuclear factor kappa- ligand (RANKL). Although there have been several reports on the denosumab, there has been no study on the relationship among bone turnover markers, serum Ca, 1,25(OH)₂D₃, and PTH in Japanese osteoporotic patients. Here, we report the short-term study of those markers in denosumab alone group and in bisphosphonate (BP) pre-treated group.

Consequently, denosumab administration alone caused: 1) strong inhibitory effects on bone resorption from as early as 1 week, 2) a slight decrease in Calcium (Ca) at 1 week and 1 month and a significant increase in 1,25(OH)₂D₃ and PTH at 1 week before a gradual decrease, and 3) mild inhibitory effects on bone formation during the observation period. On the other hand, BP pre-treatment resulted in: 1) further significant inhibition of bone resorption markers: urinary NTX and serum TRAP-5b, 2) a slight decrease in bone formation markers: BAP and P1NP, 3) a slight increase in Ca at 1 week and 1 month, and 4) no marked change in 1,25(OH)₂D₃ and PTH. These findings suggest that denosumab has a strong inhibitory effect of bone resorption, although its inhibitory effects on bone formation are apparently weaker than those caused by BP, potentially due to the functional differences between denosumab and BP.

We have the following recommended reviewers.

1) Professor Masato Sato
Department of Orthopaedic Surgery, Surgical Science, Tokai University School of Medicine, 143 Shimokasuya, Isehara, Kanagawa, 259-1193 Japan.
Email: sato-m@is.icc.u-tokai.ac.jp

2) Professor Seneki Kobayashi
Department of Orthopaedic Surgery, Suwa Red Cross Hospital, Suwa, Japan.
Email: seneki@suwa.jrc.or.jp

These findings absolutely contribute to the broad readers who are interested in not only osteoporosis, but also general physicians and Orthopaedic surgeons. Actually, our study has been approved by the Clinical Trials #Deno-PTH2365. Therefore, we strongly hope that this manuscript will be also published in BMC Endocrine Disorders.
Thank you very much for your attention and we look forward to hearing from you very soon.

Sincerely,

Yukio Nakamura,