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Randomized clinical trial comparing the efficacy of daily, weekly and monthly administration of vitamin D_3

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The main objective of the present study was to demonstrate efficacy and safety of three different vitamin D_3 treatment protocols with the same cumulative dose in vitamin D-deficient subjects. Adult subjects with vitamin D deficiency (25OHD<20 ng/ml), were included according to the inclusion and exclusion criteria. A daily single dose of 1000 IU (group DD1K) to a once weekly dose 7000 IU (group WD7K), or monthly dose of 30,000 IU (group MD30K) of vitamin D_3 were administered for 12-weeks. The comparative efficacy and safety profiles of these selected maintenance doses of vitamin D_3 has been evaluated in a prospective, randomized clinical trial. Additional to safety parameters, the measurements of 25OHD and PTH were completed in every 4 weeks. The treatment efficacy was compared between groups by inclusion levels (i.e. <10 ng/ml and 10-20 ng/ml initial plasm 25OHD values at screening). The dose-response were similar in these three groups, 13.0±1.5; 12.6±1.1 and 12.9±0.9 ng/ml. Thus the treatment of vitamin D-deficient subjects with different treatment regimens of 1000 IU/daily dose were judged to be equally effective in restoration of 25OHD values to above 20 ng/ml. The increase of 25OHD in the group with "low" (<10 ng/ml) initial values was significantly higher (14.05-20.9 ng/ml) by the end of the treatment period in treatment group than that in the group with "moderately-insufficient" (10-20 ng/ml) baseline values (11.54-14.9 ng/ml). The calculated efficacy relative to the baseline resulted in Effnd=1.72-2.66 of subjects with the "low" and Effnd=0.75-0.92 in moderately deficient subjects. Outcomes of the present RCT investigation demonstrated similar efficacy and safety profile of daily, weekly and monthly dosing equivalent of 1000 IU/day vitamin D_3. The present study utilized vitamin D_3 tablets commercially available for the public with selected dosing schedules to achieve the best adherence to treatment goals.

Speaker Biography

Bela E Toth MD, PhD, MBA, has her academic background based on neuroendocrine and cell biology research (Semmelweis University, Neuroendocrine research group at Academy of Sciences Hungary; Rudolph Magnus Institute of Pharmacology, Utrecht: The Netherlands; Dept. of Molecular and Cell Biology: Penn State University, USA). She was academically appointments as a university Lecturer (Medical School) and Invited lecturer for graduate and postgraduate education and recently as an Associate Professor, Head of Department of Pharmaceutical Surveillance and Economy at Debrecen University, teaching pharmacovigilance, pharmaceutical business-management, and drug development. Her clinical research experience is based on clinical operation management and clinical quality site management including senior level consultancy for pharmaceutical industry (research /project management, drug development, medical affairs) and clinical operational head. The research projects covered the range of development phases (I/II to III-IV) including specific areas such as bioequivalence and post-marketing safety trials as well.

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