

## Supplemental Material

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### Description and safety consideration of the vitamin D dose regimen

#### Vitamin D Dose Regimen

The 600,000 IU single dose regimen for vitamin D supplementation has been employed with excellent safety in clinical trials and in various populations including the extreme elderly (1-3). The largest clinical trial of this regimen was annual dosing for 2 years in 2256 elderly community-based women at risk for fracture demonstrating its long term clinical and laboratory-based safety (2). Short-term laboratory and clinical safety data in youthful subjects at 3, 30, 50 and 90 days post dose are also excellent (3).

#### References

1. Sanders KM, Stuart AL, Williamson EJ, et al. [Annual high-dose oral vitamin D and falls and fractures in older women: a randomized controlled trial.](#) JAMA. 2010; 303(18):1815-22.
2. Heikinheimo RJ, Inkovaara JA, Harju EJ, et al. [Annual injection of vitamin D and fractures of aged bones.](#) Calcif Tissue Int. 199 ;51(2):105-10.

3. Cipriani C, Romagnoli E, Scillitani A, et al. [Effect of a single oral dose of 600,000 IU of cholecalciferol on serum calcitropic hormones in young subjects with vitamin D deficiency: a prospective intervention study.](#) J Clin Endocrinol Metab. 2010 ;95(10):4771-7.

Table 1: Subject characteristics at screening visit

	High phosphate group	Low phosphate group	significance
Age (y)	23.1 ± 3.2	23.4 ± 3.4	ns
Female sex (%)	40	40	
BMI	22.6 ± 3.1	23.0 ± 3.4	ns
Mean systolic 24h ABPM, mm Hg	120 ± 7	122 ± 8	ns
Mean diastolic 24 hour ABPM, mm Hg	76 ± 7	75 ± 8	ns
Mean 24 hour pulse rate, bpm	69 ± 8	66 ± 7	ns
<b>Blood and plasma:</b>			
Na (mmol/L)	140 ± 3	139 ± 4	ns
K (mmol/L)	4.1 ± 0.4	4.2 ± 0.5	ns
Chloride (mmol/L)	105 ± 5	104 ± 6	ns
Ionized calcium (mmol/L)	1.21 ± 0.10	1.20 ± 0.11	ns
Fasting phosphate (mmol/L)	1.10 ± 0.21	1.14 ± 0.16	ns
HCO <sub>3</sub> <sup>-</sup> (mmol/L)	24.5 ± 1.2	24.8 ± 1.2	ns
Creatinine (umol/L)	64 ± 9	66 ± 10	ns
Intact PTH (ng/ml)	39 ± 8	40 ± 9	ns
25(OH)D (nmol/L)	68 ± 10	70 ± 11	ns
<b>Urine (mmols/24h)</b>			
Na	80 ± 15	78 ± 12	ns
K	61 ± 9	58 ± 10	ns
calcium	3.4 ± 0.8	3.2 ± 0.6	ns
phosphate	23.6 ± 6.1	26.1 ± 7.1	ns
creatinine	7.0 ± 0.5	6.8 ± 0.7	ns
Net acid excretion (meq/24h)	34 ± 10	29 ± 11	ns
Albumin (mg/24h)	11 ± 8	10 ± 12	ns

Values in table are means ± standard deviation.