A Phase II RCT of High-Dose Vitamin D Supplementation for Androgen Deprivation Therapy (ADT)-Induced Bone Mineral Density (BMD) Loss among Older Prostate Cancer (PCa) Patients

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OBJECTIVE: The aim of this phase II RCT is to determine the preliminary efficacy of weekly, high-dose vitamin D (50,000 IU/week) on ADT-induced bone loss on prostate cancer patients.

INTRODUCTION: ADT use causes hypogonadism, which can result in accelerated bone loss and fragility fractures. Vitamin D (VITD) may protect against bone loss; however it remains unclear if the recommended daily allowance (RDA) of VITD is sufficient to reduce bone loss or whether higher doses are needed.

METHODS: A total of 59 PCa patients aged ≥60 years old with VITD insufficiency (<32 ng/ml) and starting ADT were enrolled.

- Subjects were randomized into 2 arms: 1) High-Dose Vitamin D (600 IU/daily plus 50,000 IU/weekly), or 2) the RDA of Vitamin D (600 IU/daily plus placebo weekly) for 24 weeks. All subjects also received 100% of the RDA for calcium (1,000 mg/day).
- Bone mineral density (BMD) was assessed at the Total Hip and Lumbar Spine via DXA pre- and post-intervention. Bone biomarkers were also assessed pre- and post-intervention.
- Changes were determined by ANCOVA analysis and controlled for corresponding baseline levels.

RESULTS

Fig 1: 25-OH Vitamin D

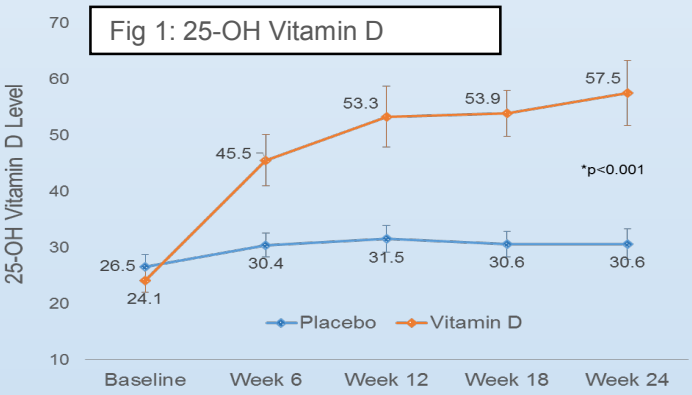


Fig 2: Serum Calcium

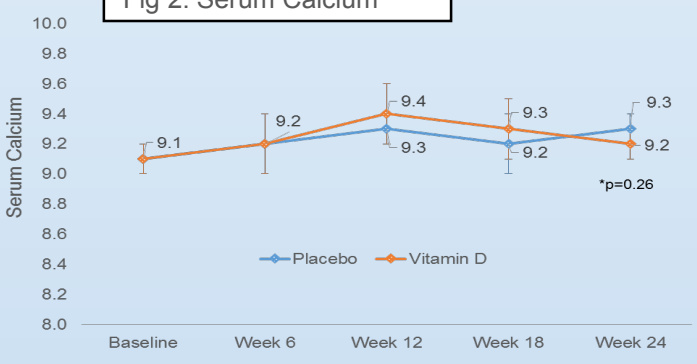


Fig 3: Change in Bone Mineral Density

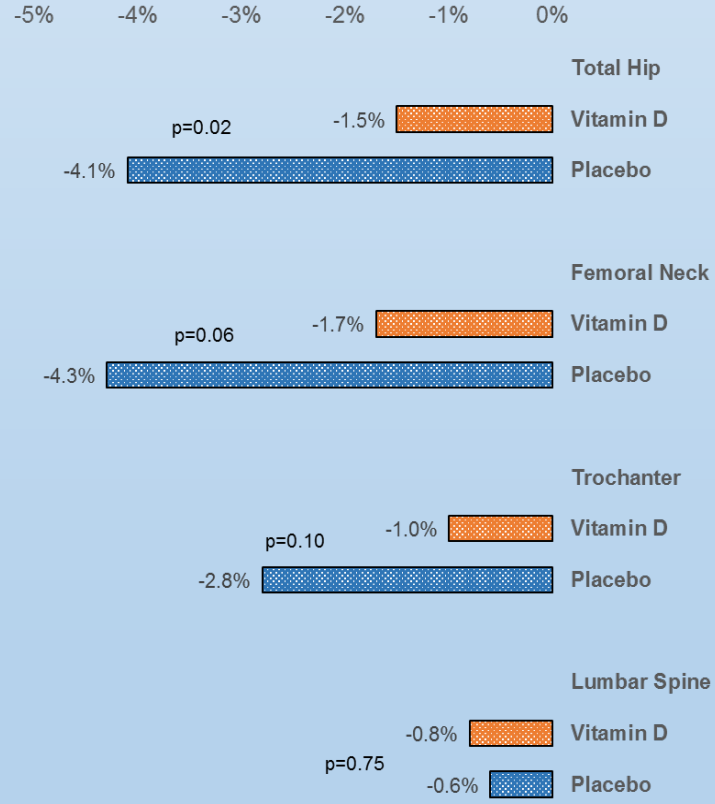


Fig 4: Bone Biomarkers

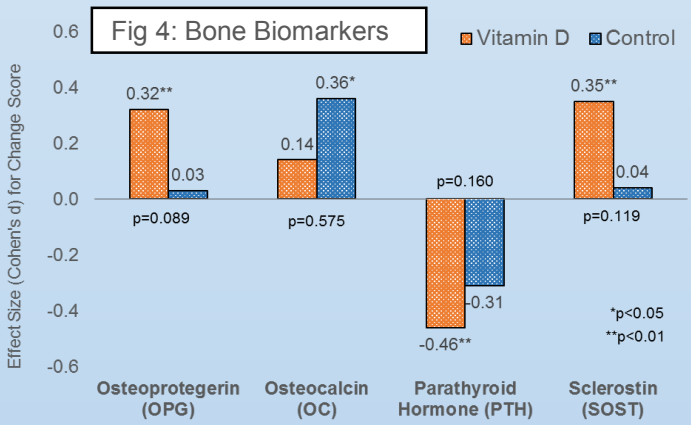
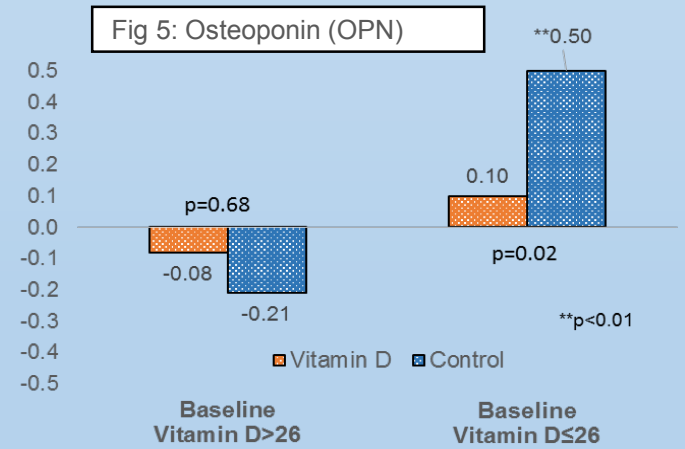


Fig 5: Osteoponin (OPN)



CONCLUSIONS AND FUTURE DIRECTIONS

- High-dose vitamin D supplementation produced significantly greater reductions in hip BMD loss among older PCa patients receiving ADT compared to the RDA of vitamin D.
- The rate of BMD loss was significant; control subjects lost approximately 4% hip BMD in less than six months.
- Clinically, higher doses of vitamin D may be necessary to effectively prevent ADT-induced bone loss
- A definitive phase III RCT is needed to confirm these findings.

This project was funded by NCI R21CA175793, K07CA168911 & UG1CA189961. Bio-Tech Pharmacal Inc. supplied all agents.