# High-Dose Vitamin D Supplementation for ADT-Induced Bone Loss in Older Prostate Cancer Patients

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 60 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

**Inclusion Criteria:**

* Be diagnosed with Stage I-IV prostate cancer without metastases to bone (lymph node involvement and prior diagnosis of a primary cancer is allowed) * Be age 60 years or older * Be starting ADT or have received their first ADT treatment in the past 3 months, with a total of at least 6 planned months of treatment (both luteinizing hormone-releasing hormone \[LHRH\] antagonists and LHRH agonists are permitted) * Have a total serum vitamin D between 10 and 27 ng/ml * Have a total serum calcium of less than or equal to 10.5 mg/dl * Have a normal GFR (glomerular filtration rate \> 30ml) * Agree not to take calcium and/or vitamin D supplements for the duration of the intervention other than those provided by the study * Be able to provide written informed consent * Be able to swallow pills and capsules * Be able to speak and read English

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**Exclusion Criteria:**

* Have long term (greater than 3 months) use of any pharmacologic bone-modifying agent including but not limited to oral or intravenous (IV) bisphosphonates, denosumab, or teriparatide prior to enrollment * Have a diagnosis of stage IV chronic kidney disease * Have a diagnosis of grade II or greater hypercalcemia (serum calcium greater than 11.5 mg/dl) * Have a history of hypercalcemia or vitamin D toxicity/sensitivity

## Conditions & Interventions

**Interventions:**
PROCEDURE: Biospecimen Collection, DIETARY_SUPPLEMENT: D Vitamin, PROCEDURE: Dual X-ray Absorptiometry, DRUG: Placebo Administration, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration

**Conditions:**
Stage I Prostate Cancer AJCC v8, Stage II Prostate Cancer AJCC v8, Stage III Prostate Cancer AJCC v8, Stage IVA Prostate Cancer AJCC v8

## More Information

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**Principal Investigator:**

**Phase:** PHASE3

**IRB**
**Number:**

**System ID:** NCT05838716

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