

## FAST FACTS

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### **URCC22053: High-dose Vitamin D Supplementation for ADT-Induced Bone Loss in Older Prostate Cancer Patients (ViPER)**

#### **Inclusion Criteria**

- 1) Be diagnosed with Stage I-IV prostate cancer without metastases to bone (lymph node involvement and prior diagnosis of a primary cancer is allowed).
- 2) Be age 50 years or older.
- 3) Be starting ADT or have received their first ADT treatment in the past 6 months, with a total of at least 6 planned months of treatment remaining (both luteinizing hormone-releasing hormone (LHRH) antagonists and LHRH agonists are permitted).
- 4) Have a total serum vitamin D between 10 and 32 ng/ml.
- 5) Have a total serum calcium of less than or equal to 10.5 mg/dl.
- 6) Have a normal GFR (glomerular filtration rate >30 ml).
- 7) Agree not to take calcium and/or vitamin D supplements for the duration of the intervention other than those provided by the study.
- 8) Be able to provide written informed consent.
- 9) Be able to swallow pills and capsules.
- 10) Be able to speak and read English.

#### **Exclusion Criteria**

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

## STUDY SCHEMA

