STUDY SCHEMA



SCREENING

- Patients with prostate cancer
- Age 60 years or older
- Serum Vitamin D levels between 10 and 27 ng/ml
- Beginning ADT (or within 3 months of initiating ADT)

BASELINE - A1 (week 0)

- Patient-Reported Outcomes/Questionnaires
- Blood draw
- DXA Scan
- Randomization to one of two groups

Arm 1

- Daily vitamin D (800IU) and calcium (600mg) supplement
- Weekly high-dose vitamin D (50,000IU)

Arm 2

- Daily vitamin D (800IU) and calcium (600mg) supplement
- Weekly placebo

SAFETY CHECK-A2 (week 8)

Blood draw for vitamin D and calcium levels

SAFETY CHECK-A3 (week 16)

• Blood draw for vitamin D and calcium levels

MIDPOINT VISIT- A4 (week 24)

- Patient-Reported Outcomes/Questionnaires
- Blood draw
- DXA Scan

SAFETY CHECK-A5 (week 38)

• Blood draw for vitamin D and calcium levels

FINAL VISIT- A6 (week 52)

- Patient-Reported Outcomes/Questionnaires
- Blood draw
- DXA Scan

4.0 PARTICIPANT ELIGIBILITY

4.1 Inclusion Criteria

Participants must:

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

4.2 Exclusion Criteria

Participants must NOT:

- 4.2.1 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.
- 4.2.2 Have a diagnosis of stage IV chronic kidney disease.
- 4.2.3 Have a diagnosis of grade II or greater hypercalcemia (serum calcium greater than 10.5 mg/dl)
- 4.2.4 Have a history of hypercalcemia or vitamin D toxicity/sensitivity.