

# Improving Cancer-related Fatigue, Sexual Dysfunction and Quality of Life in Older Men With Cancer and Androgen Deficiency

NCT04301765

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Seattle Institute for Biomedical and Clinical Research
<b>Enrollment</b>	230 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Men with active solid or hematologic (blood) cancers who have received or are receiving chemo- and/or radiation therapy. Patients who have no evidence of disease (NED) for 60 months or less, which means that they are <60 months from their last treatment (chemotherapy and/or radiation therapy) will be included.
  - Age: 55 years and older
  - Life expectancy of at least 6 months.
  - Serum testosterone, measured by mass spectrometry (gold standard method), of <348 ng/dl and/or free testosterone <70 pg/ml. The lower limits of the normal range for total testosterone in healthy men is 348 ng/dL and the lower limits of free testosterone is <70 pg/ml in the Framingham Heart Study sample. As sex hormone binding globulin levels may be elevated in some men with cancer (resulting in elevation in total testosterone level), some of these symptomatic men may still be hypogonadal despite having total testosterone above this cut-off limit, but their free testosterone levels may still be below the lower limit of normal. Thus, men with free testosterone <70 pg/mL will be included.
  - Fatigue. Fatigue was selected as it is a highly prevalent symptom in cancer patients. Fatigue will be defined as a score on FACIT-Fatigue subscale of <40, which best divides cancer patients from the general population with accuracy.
- ... and 1 more (see full listing online)

### Exclusion (13)

- Men with current or prior history of prostate, breast, testicular, or adrenal cancers.
  - Use of anabolic agents (testosterone, DHEA, growth hormone) within the past 6 months
  - Hematocrit >48%, serum creatinine >2.5 mg/dL
  - PSA >4 ng/ml; nodule or induration on digital rectal exam
  - Severe untreated sleep apnea
- ... and 8 more (see full listing online)

## Locations (3 total)

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Georgia Cancer Center at Augusta University, Augusta, Georgia, United States  
Brigham and Women's Hospital, Boston, Massachusetts, United States  
Veterans Affairs Puget Sound Health Care System, Seattle, Washington, United States