ARACOG: A Randomized Phase II Study of Androgen Receptor Directed Therapy on COGnitive Function in Patients Treated with Darolutamide or Enzalutamide

Status: Recruiting

Eligibility Criteria

Sex: Male
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features - castration-resistant prostate cancer defined as 3 PSA rises at least 1 week apart, with the last PSA >2 ng/mL, while on treatment - testosterone level of <50 ng/dL - able to walk and care for self, but unable to work - able to read & speak English - able to swallow study tablets whole

Exclusion Criteria:

- prior chemotherapy for treatment of CRPC. Men who received chemotherapy for castrate-sensitive prostate cancer are eligible provided chemotherapy was completed more than 6 months ago - prior treatment with specific drugs (study staff will review) - radiation treatment for more than 21 days during enrollment in the study - neurological diseases that affect thinking (dementia, seizures, etc.) - chronic use of opiates that affects thinking - significant history of falls or risk of falls

Conditions & Interventions

Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Castration Resistant Prostate Cancer, CRPC, Metastatic Prostate Cancer, Prostate Cancer, Prostate Cancer

More Information

Description: To compare the effects of treatment with enzalutamide (ENZ) versus darolutamide (DARO) on the cognitive function of men with non-metastatic and metastatic castration-resistant prostate cancer (mCRPC) by comparing the change in the maximally changed cognitive domain from baseline in patients in each study arm by 24 weeks.
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