A randomized, double-blind, placebo-controlled Phase 3 study of darolutamide plus androgen deprivation therapy (ADT) compared with placebo plus ADT in patients with high-risk biochemical recurrence (BCR) of prostate cancer

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- diagnosis of adenocarcinoma of prostate - treated with surgery and/or radiation therapy - Serum testosterone 150 ng/dL or more - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- small cell, ductal or 50% or more component of neuroendocrine carcinoma of the prostate - brain metastasis - any other type of cancer (other than adequately treated basal cell or squamous cell skin cancer, superficial bladder cancer, or any other cancer in situ currently in complete remission) within 5 years - study staff will review

Conditions & Interventions

Interventions:
Other: ADT, Drug: Darolutamide (BAY1841788, Nubeqa), Other: Placebo matching darolutamide
Conditions:
Cancer
Keywords:
Prostate Cancer, Recurrent Prostate Cancer, Clinics and Surgery Center (CSC)

More Information

Description: ADT is a systemic therapy called hormone therapy which reduces the androgen hormone (testosterone) levels to prevent prostate cancer cells from growing. This study is being done to learn more about a new drug called darolutamide given in combination with ADT for prostate cancer.
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