CASPAR - A PHASE III TRIAL OF ENZALUTAMIDE AND RUCAPARIB AS A NOVEL THERAPY IN FIRST-LINE METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

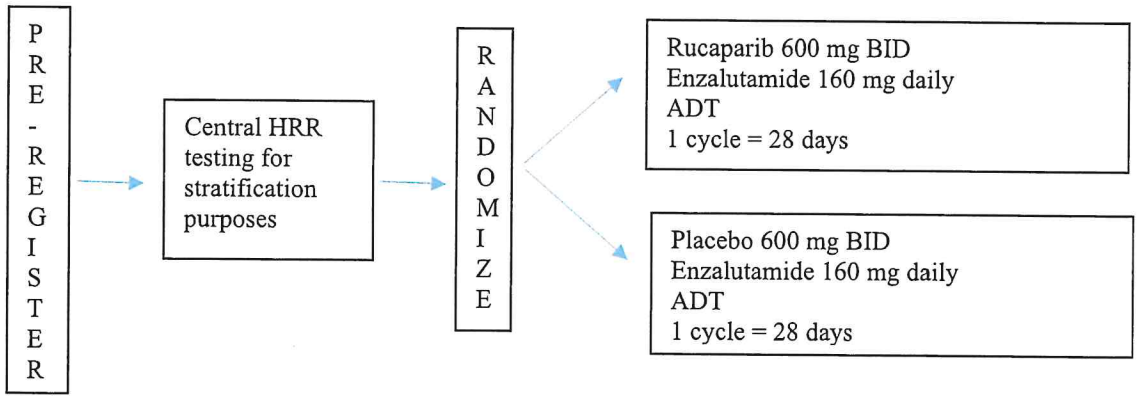
Eligibility Criteria (see Section 3.0)

Histologic/cytologic documentation of prostate adenocarcinoma
Tissue available per Section 3.2.1
Progressive disease per Section 3.2.1
Measurable or non-measurable mets disease
No prior treatment per Section 3.2.3
Age ≥ 18 years
ECOG PS 0-2
No comorbid conditions per Section 3.2.7
No medications known or suspected to have a drug interaction w/enzalutamide or rucaparib

Required Initial Laboratory Values

Absolute neutrophil count (ANC): ≥ 1500/mm^3
Platelet count: ≥ 100,000/mm^3
Hemoglobin ≥ 10 g/dL
Serum testosterone ≤ 50 ng/ dl (≤ 1.73 nmol/L)
Serum Creatinine: ≤ 1.5 x ULN
Total bilirubin: ≤ 1.5 x ULN
AST/ALT: ≤ 2.5 x ULN

Schema



For all patients, treatment is to continue until disease progression or unacceptable adverse event. Patients will be followed for 5 years or until death, whichever comes first.

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.