Version 09/13/21 (Add. #2)

NCI National Clinical Trials Network

EA8183/ERADICATE

For Patients with Prostate Cancer

EA8183 Available Through ECOG-ACRIN Cancer Research Group

A Phase III Double Blinded Study of Early Intervention after Radical Prostatectomy with Androgen Deprivation Therapy with or without Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE)

Patient Population

See Section 3.0 for Complete Eligibility Details

Preregistration (Step 0):

- Age ≥ 18 years
- Must have undergone a radical prostatectomy (RP) completed at least 2 weeks prior to Step 0 preregistration
- Must meet one of the Decipher Score criteria outlined per protocol (i.e., criteria for patients with a Decipher Score obtain through standard of care testing outside the protocol prior to registration to Step 0, OR criteria for patients without a previous Decipher Score)
- Must not have any previous treatment with androgen deprivation therapy (ADT), chemotherapy, or other physician prescribed systemic therapy for treatment of their prostate cancer (prior bicalutamide is permitted)

Randomization 6-24 weeks from RP (Step 1):

- Adequate lab values; Decipher Score > 0.6; ECOG PS 0-2
- No pathologic evidence of pelvic lymph node involvement
- Must not have uncontrolled intercurrent illness per protocol (i.e., ongoing/active infection, symptomatic congestive heart failure (NYHA Class III/IV), unstable angina pectoris, cardiac arrhythmia, etc.)
- A prior/concurrent malignancy within 5 years of Step 1 randomization where natural history/treatment does not have the potential to interfere with the safety/efficacy assessment of the investigational regimen is permitted
- HIV, HBV, HCV patients are permitted per protocol
- Must be able to take oral medications
- Must have a PSA ≤ 0.2 ng/mL obtained within 2 weeks prior to Step 1 randomization
- Must not have pre or post-operative radiographic evidence of cancer recurrence or metastasis by abdominal and pelvic imaging per protocol (within 24 weeks of Step 1 randomization)

Treatment Plan

See Section 5.0 for Complete Treatment Details

- Double-blinded trial (randomized to Arm X)
- 1 cycle= 28 days

Arm A (ADT plus placebo):

- Relugolix 120 mg PO once daily (single initial loading dose of 360 mg PO), OR
- Goserelin, leuprolide, triptorelin, or degarelix by injection per protocol, PLUS placebo (2 pills in the morning and 2 pills in the evening (1200 mg total per day) daily for 48 weeks

Arm B (ADT plus darolutamide):

- Relugolix 120 mg PO once daily (single initial loading dose of 360 mg PO), OR
- Goserelin, leuprolide, triptorelin, or degarelix by injection per protocol, PLUS darolutamide (2 pills in the morning and 2 pills in the evening (1200 mg total per day) daily for 48 weeks

Radiation Treatment:

- Intent to deliver adjuvant radiation therapy must be declared before randomization
- Radiotherapy should be delivered over approximately 7-8 weeks
- Adjuvant radiotherapy to 64.8-66.6 Gy at 1.8 Gy/36-37 fractions to the prostate bed
  - ◊ Pelvic nodal radiation 45.0-50.4 Gy at 1.8 Gy/25-28 fractions is allowed
- Salvage radiotherapy to 64.8-70.2 Gy at 1.8Gy/36-39 fractions to the prostate bed
  - ◊ Pelvic nodal radiation 45.0-50.4 Gy at 1.8 Gy/25-28 fractions is allowed
- Photon treatment; 3D-CRT, IMRT, VMAT. Image guidance is required

Study Chair:
Alicia K. Morgans, MD, MPH

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

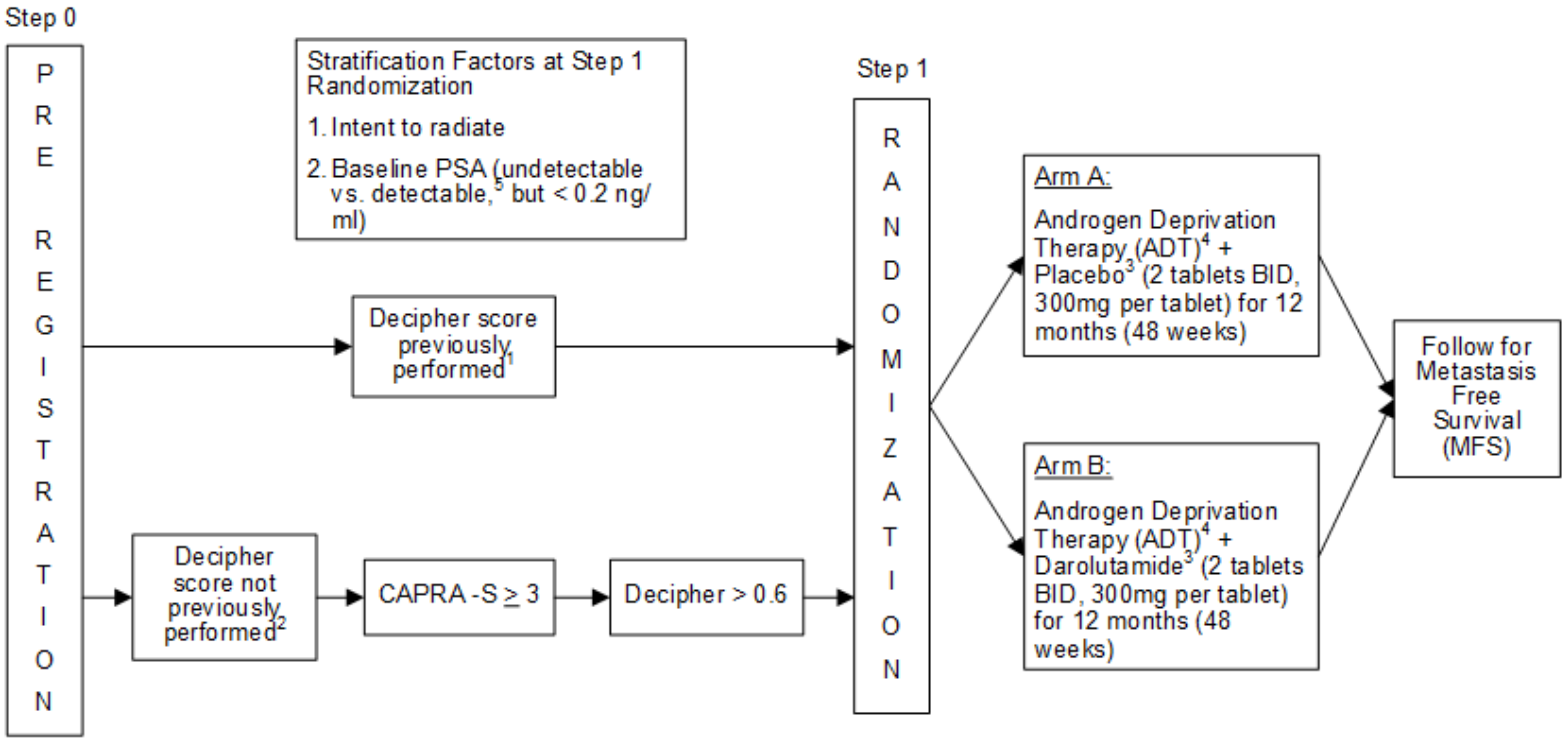
ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

ECOG-ACRIN cancer research group
Reshaping the future of patient care

EA8183

Schema



Accrual Goal: 810
Cycle Duration: 28 days

1. Patients with a Decipher score previously performed by through standard of care testing outside the protocol with a score of > 0.6 are eligible and may proceed from pre-registration directly to randomization after uploading Decipher score to Medidata Rave.
2. For patients who do not already have a completed Decipher test, the calculated CAPRA-S score must be ≥ 3 and the post registration Decipher Biosciences assessment must determine Decipher score to be > 0.6.
3. Patients receiving post-operative adjuvant radiation (XRT) can receive it anytime within 52 weeks of prostatectomy.
4. ADT is administered as 1, 3, 4, and 6-month formulations. Some formulations may not be available for specific ADT choices; see section 5.
5. Detectable PSA is defined as 0 > PSA > 0.2.

NOTE: Please note that when a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm X. The patient will actually be randomized to Arm A or B, but as this is a double-blind trial, that information cannot be displayed.