Version 10/13/20

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, ECOG PS 0-2
- Must have undergone a radical prostatectomy (RP) and must be preregistered to Step 0 6-12 weeks after RP
- Must not have any previous treatment with androgen deprivation therapy (ADT), chemotherapy, or other physician prescribed systemic therapy for treatment of their prostate cancer
- Must not have pathologic evidence of pelvic lymph node involvement
- Must not have uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure (NYHA Class III/IV), unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements
- Patient with a prior/concurrent malignancy within 5 years of registration, whose natural history/treatment does not have the potential to interfere with the safety/efficacy assessment of the investigational regimen are eligible
- Patients with no previous Decipher score: tumor tissue specimen from RP must be ready to be shipped within 20 weeks post-surgery

Randomization within 24 weeks of surgery (Step 1):

- Adequate lab values; Decipher score > 0.6
- For patients who did not have a Decipher score previously performed, patients must also have a CAPRA-S score ≥ 3 (see protocol for details)
- Must have undetectable PSA obtained within 2 weeks prior to randomization
- Must not have pre or post-operative radiographic evidence of cancer recurrence or metastasis by abdominal and pelvic imaging per protocol (after prostatectomy and within 24 weeks prior to randomization)

Treatment Plan

See Section 5.0 for Complete Treatment Details

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

Arm A:

- ADT injections of goserelin, leuprolide, triptorelin, or degarelix in 3-month (4 total during study), 4-month (3 total),1-month (12 total), or 6-month (2 total) depot formulation, plus placebo administered by mouth daily for 52 weeks
  - ◊ Placebo is 2 pills in the morning and 2 pills in the evening (1200mg total per day); taken with food and swallowed whole

Arm B:

- ADT injections of goserelin, leuprolide, triptorelin, or degarelix in 3-month (4 total during study), 4-month (3 total),1-month (12 total), or 6-month (2 total) depot formulation, plus darolutamide administered by mouth daily for 52 weeks
  - ◊ Darolutamide is 2 pills in the morning and 2 pills in the evening (1200mg total per day); taken with food and swallowed whole

Radiation Treatment:

- Intent for adjuvant radiation therapy should be decided 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

Study Chair:
Alicia K. Morgans, M.D., M.P.H

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!

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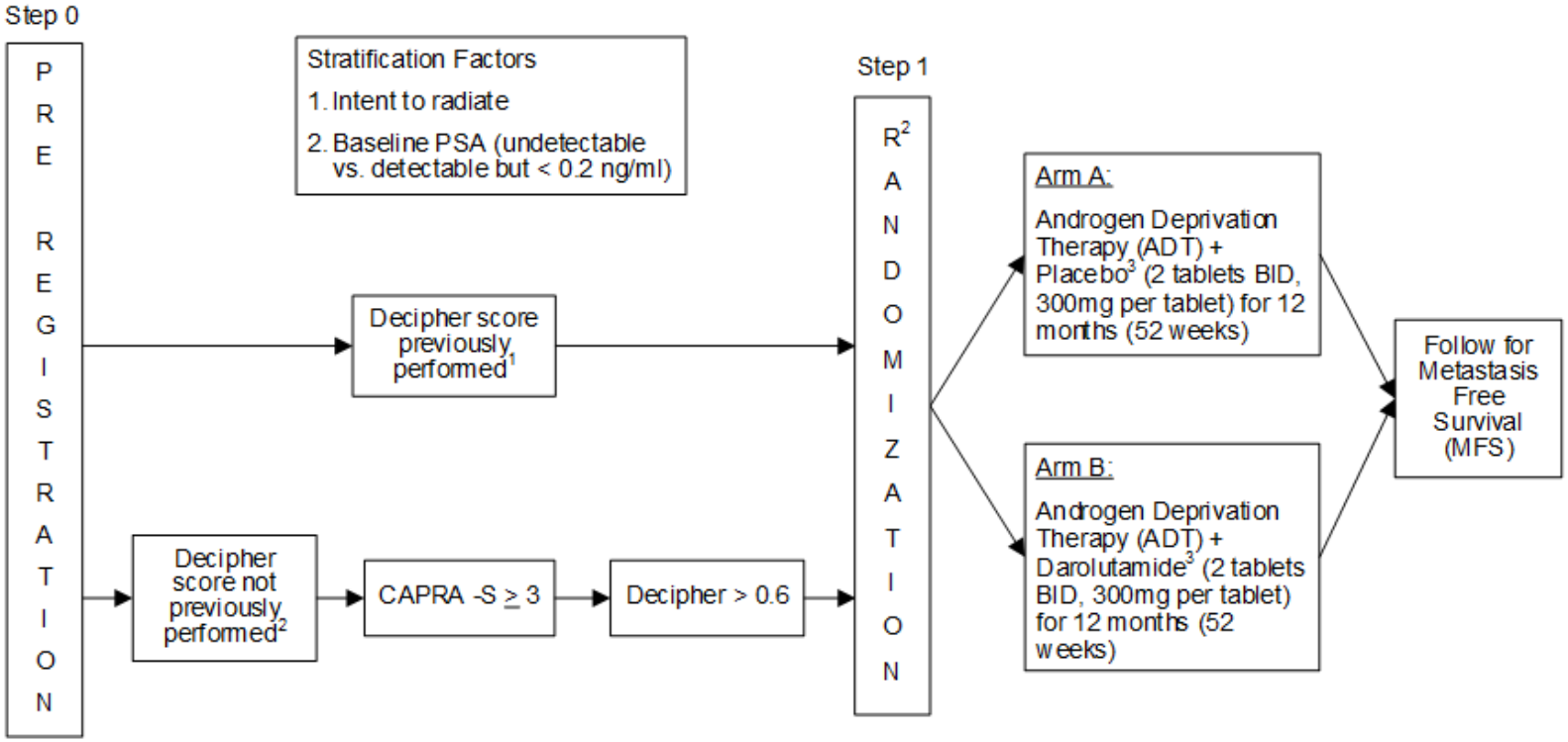
ECOG-ACRIN cancer research group
Reshaping the future of patient care

EA8183

Schema



Accrual Goal: 810

1. Patients with a Decipher score previously performed by Decipher biosciences 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 through standard of care testing, 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.