# For Women with Dense Breasts

**EA1141 Available Through ECOG-ACRIN Cancer Research Group**

Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women with Dense Breasts

## Patient Population

See Section 3.0 for Complete Eligibility Details

- Must be women ages 40 to 75 years and scheduled for routine screening DBT
- Must not be pregnant or breast-feeding
- Breast density must be known; must have mammographically dense breasts (ACR BI-RADS lexicon categories c or d [heterogeneous or extreme fibroglandular tissue]) on their most recent prior screening
- Must be asymptomatic for breast disease and undergoing routine screening
- Must have no known breast cancer (DCIS or invasive), not currently undergoing treatment for breast cancer, or planning surgery for a high risk lesion (ADH, ALH, LCIS, papilloma, radial scar)
- Must not be taking chemoprevention for breast cancer
- Must not have undergone screening breast ultrasound within 12 months prior to randomization
- Must not have previously had a breast MRI or molecular breast imaging (MBI, MIBI)
- Must agree to not undergo screening ultrasound (of breast) for the duration of the 1 year study period
- Must not be suspected of being at high-risk for breast cancer (ACS breast MR screening recommendations; lifetime risk of ≥ 20-25%)
- Must be able to undergo breast MRI with contrast
  - No history of untreatable claustrophobia or sickle cell disease
  - No presence of non MR compatible metallic objects/ metallic objects that would make MRI a contraindication; no contraindication to intravenous contrast administration
  - No known allergy-like reaction to gadolinium or moderate/severe allergic reactions to 1 or more allergens defined by ACR
  - No known/suspected renal impairment
  - Weight less than or equal to the MRI table limit
  - No prior CESM or CEDM
  - No women with breast prosthetic implants

## Treatment Plan

See Section 5.0 for Complete Treatment Details

All patients will undergo both DBT and AB-MR within 30 days following randomization. Although it is optimal to perform the DBT and AB-MR on the same day, sites may perform the DBT and AB-MR within 24 hours of each other as long as the two interpreting radiologists remain blinded to the results of the other modality. No biopsy should be performed until both DBT and AB-MR have been completed. All suspicious findings on either DBT or AB-MR should be biopsied regardless of the recommendation of the other modality

**Arm A:** DBT followed by AB-MR (same day or within 24 hours of each other, as long as any workup needed from the DBT [spot compression/magnification views and/or ultrasound] is completed prior to the AB-MR)

**Arm B:** AB-MR followed by DBT (same day or within 24 hours of each other)

**Notes:**

- Recommendations for findings on DBT will be based on ACR guidelines; recommendations for findings on AB-MR will be based on the Society of Breast MRI interpretive guidelines
- The interpreting radiologist may refer to mammograms/ultrasounds from previous years
- All women will undergo DBT and AB-MR at 1 year in the same order as the baseline DBT and AB-MR; follow-up will be conducted via phone per protocol
- Prior to patient enrollment, all participating scanners must be ACR accredited for Breast MRI; all interpreting physicians must have completed the Society of Breast MRI for AB-MR training
- DBT technique will be defined as per local site standard of care (i.e., tomosynthesis views in the CC or MLO views or both views with either a 2D full field digital mammogram or synthetic 2D views)
- Tissue collection and analysis for all cancer
- Patients will be asked (not required) to forgo WBUS

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**Study Chair:**
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**Co-Chairs:**
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**Patient Enrollment**

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

**Protocol Information**

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

Please Enroll Your Eligible Patients!
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**Schema**

**Randomization**

- **Arm A (DBT First)**
  - Years 0 and 1 DBT followed by AB-MR.
  - Year 0 PROGOL assessments to be completed approximately 2 weeks after screenings.

- **Arm B (AB-MR First)**
  - Years 0 and 1 AB-MR followed by DBT.
  - Year 0 PROGOL assessments to be completed approximately 2 weeks after screenings.

**Return to routine mammographic screening and follow for 3 years**

**Women ages 40–75 with dense breasts already scheduled for routine screening DBT**

**Accrual Goal = 1430**

1. Suspicious lesions detected on one or both of the modalities at the Year 0 or 1 time points will be biopsied as per local standard practice.
2. Tissue collection and analysis for all cancers detected.