Cancer Research Consortium of West Michigan
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# FAST FACTS

## EA1141: Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women with Dense Breasts

### Eligibility Criteria

1. Patients must be women ages 40 to 75 years and scheduled for routine screening DBT.
2. Women must not be pregnant or breast-feeding as gadolinium enhanced MRI and screening DBT are contra-indicated.

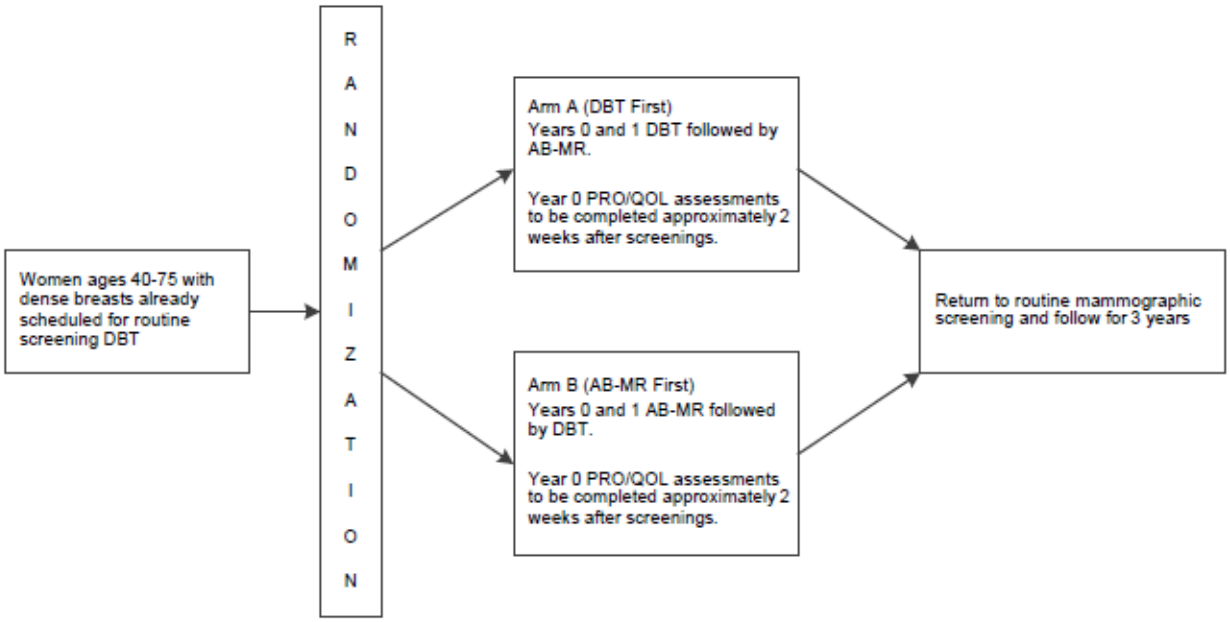
   All females of childbearing potential who are uncertain if they could be pregnant or may be pregnant or as per local site standard of practice in women undergoing DBT and MRI must have a blood test or urine study within 2 weeks prior to randomization to rule out pregnancy.

   A female of childbearing potential is any woman, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months).
3. Women of childbearing potential must be strongly advised to use an accepted and effective method of contraception or to abstain from sexual intercourse for the following year until the Year 1 AB-MR and DBT studies are performed.
4. Patient's breast density must be known; patients must have mammographically dense breasts, ACR BI-RADS lexicon categories cor d (heterogeneous or extreme fibroglandular tissue) on their most recent prior screening.
5. Patient must be asymptomatic for breast disease and undergoing routine screening.
6. Patient must have no known breast cancer (DCIS or invasive cancer), not currently undergoing treatment for breast cancer, or planning surgery for a high risk lesion (ADH, ALH, LCIS, papilloma, radial scar).
7. Patient must not be taking chemoprevention for breast cancer.
8. Patient must not have undergone screening breast ultrasound within 12 months prior to randomization
9. Patient must not have previously had a breast MRI.
10. Patient must not have previously had molecular breast imaging (MBI, MIBI)
11. Patient must agree to not undergo screening ultrasound (of breast) for the duration of the 1 year study period as screening ultrasound adds no benefit in women undergoing breast MRI
12. Patient must not be suspected of being at high-risk for breast cancer, as defined by the ACS breast MR screening recommendations (lifetime risk of ≥ 20-25%). See Appendix I.
13. Patient must be able to undergo breast MRI with contrast enhancement. Patients unable to undergo breast MRI with contrast enhancement for any reason are ineligible.

    a. No history of untreatable claustrophobia;
    b. No presence of non MR compatible metallic objects or metallic objects that, in the opinion of the radiologist, would make MRI a contraindication.
    c. No history of sickle cell disease
    d. No contraindication to intravenous contrast administration;

e. No known allergy-like reaction to gadolinium or moderate or severe allergic reactions to one or more allergens as defined by the American College of Radiology (ACR); patient may be eligible if willing to undergo pre-treatment as defined by the institution's policy and/or ACR guidance (see http://www.acr.org/quality-safety/resources/contrast-manual for reaction definition and premedication guidance);
f. No known or suspected renal impairment. Requirements for GFR prior to MRI as determined by local site standard practice.
g. Weight less than or equal to the MRI table limit;
h. No women who have had prior contrast enhanced mammography (CESM or CEDM).
i. No women who have breast prosthetic implants (silicone or saline).

**Schema**




**Pre-study parameters:**

- Blood Creatinine
- Serum or urine Pregnancy test