Alliance A011104/ACRIN 6694: Effect of Preoperative Breast MRI on Surgical Outcomes, Costs and Quality of Life of Women with Breast Cancer

Isabelle Bedrosian, MD

University of Texas MD Anderson Cancer Center

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Rationale

- Well established that breast MRI detects more disease and impacts surgical management
- Not known whether by detecting additional disease:
  - Rates of local failure are reduced
  - Rates of contralateral breast cancer are decreased
- Breast MRI may be particularly important for ER/PR negative disease which is shown to be relatively radio-resistant with higher rates of local failure after BCT
  - Detecting and surgically removing additional foci of disease may be particularly important for this group of patients.

Hypothesis

Preoperative breast MRI improves staging and selection of patients with hormone receptor negative tumors for BCT, thus lowering rates of local regional recurrence.

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Trial Endpoints

Primary

- LRR rates at 5 years between the MRI and no MRI arm

Secondary

- Rates of re-excision, including conversion to mastectomy
- Contralateral breast cancer rates
- Time to local recurrence
- Overall and disease specific survival
- MRI technical performance (sensitivity, specificity, PPV)

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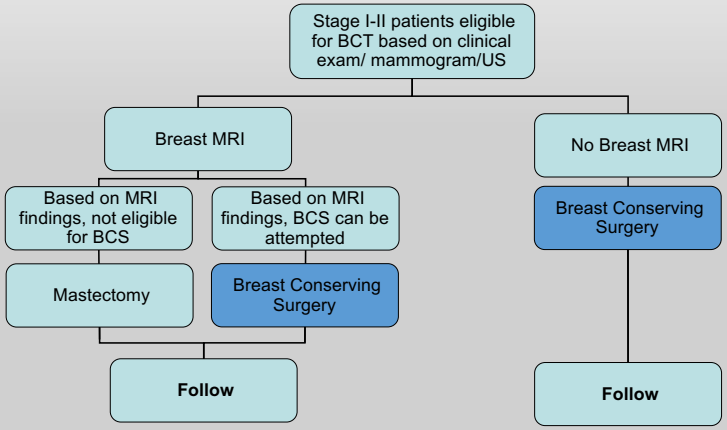
Study Schema



Sample size: 144 patients/arm

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Frequently Asked Questions (FAQs)

BRCA testing
- Not required to enroll
- If pt. referred for testing, can still enroll into trial. If later found to be BRCA +, can come off study.

MRI reimbursement
- For patients randomized to MRI arm, additional $900 will be paid by ACRIN to support image data collection and transmission
- MRI can be billed to insurance as per institutional guidelines/standards

Is prior history of contralateral breast cancer an exclusion?
- Yes

Can Spanish speaking patients enroll?
- Yes, Spanish forms available for all aspects ***except*** "Assessment of Survivor Concerns" form which will require translation to patient

Is there a patient education brochure?
- Yes, available on Alliance website (and will be on CTSU soon)

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Key Eligibility Criteria

- Women with
  - **ER/PR <10%**
  - **Any Her2**
- Stage I-II, unilateral cancer
- No previous breast cancer history
- Preoperative chemotherapy is allowed
- No plans for partial breast irradiation following lumpectomy
- No **known** BRCA carriers
- No breast MRI in the 12 months prior to enrollment

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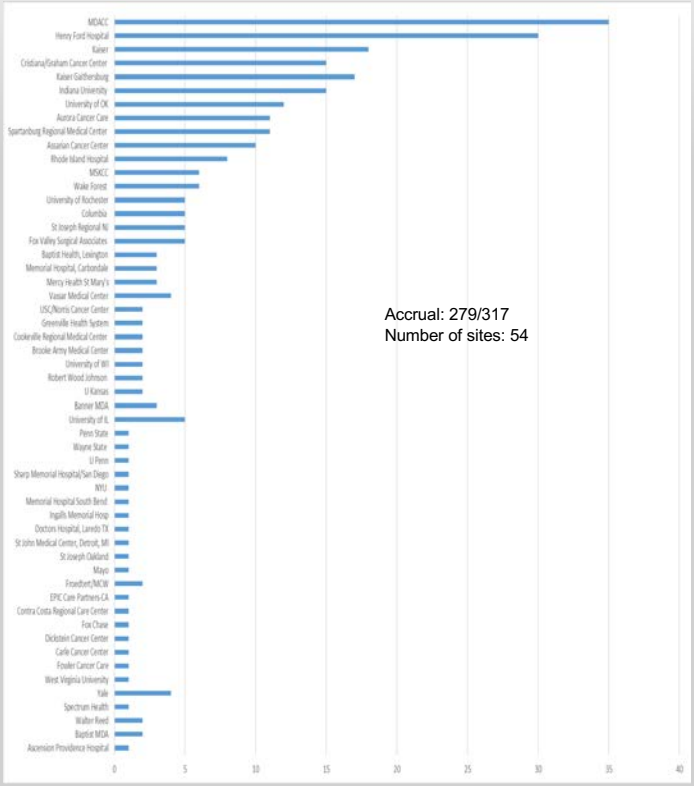
Accrual By Site



accrual data is through 02/28/2019

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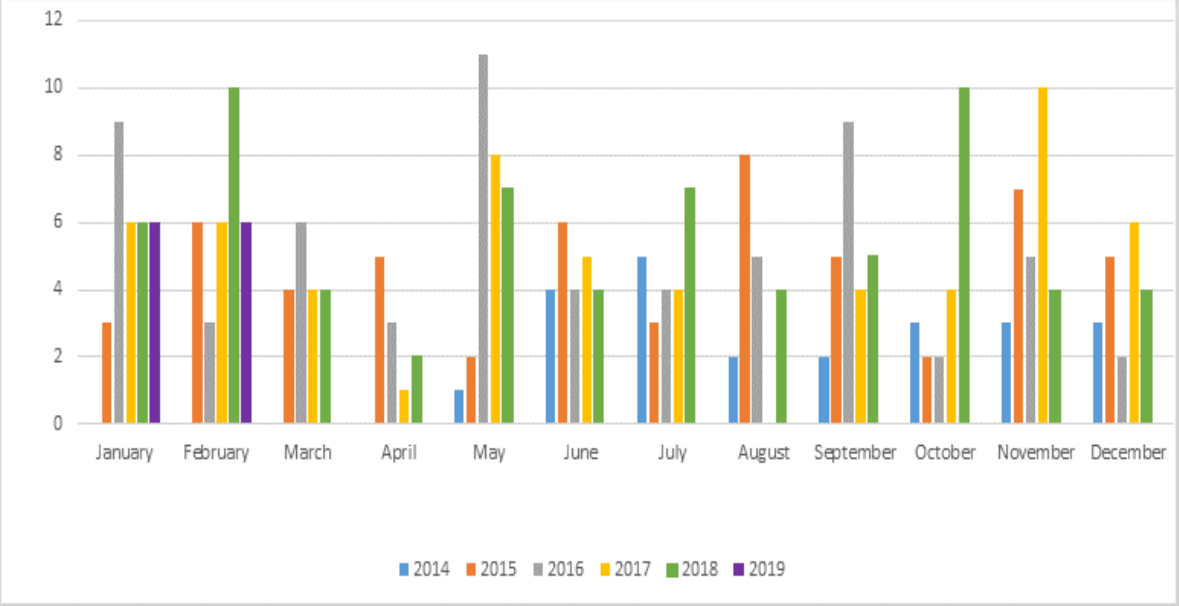
Accrual By Month



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Contact Us

Study Chair: Isabelle Bedrosian, MD, University of Texas MD Anderson Cancer Center
E-mail: ibedrosian@mdanderson.org | Phone: 713-792-3245

Protocol Coordinator: Laura Hoffman
E-mail: hoffma12@uchicago.edu | Phone: 773-834-2546