• 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.
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)
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

Sample size: 144 patients/arm

Study Schema

Stage I-II patients eligible for BCT based on clinical exam/mammogram/US

Breast MRI

Based on MRI findings, not eligible for BCS
Mastectomy

Based on MRI findings, BCS can be attempted
Breast Conserving Surgery

No Breast MRI

Breast Conserving Surgery

Follow

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

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University of Texas MD Anderson Cancer Center

Study Schema

For Enrollment After Neoadjuvant Chemotherapy

- Stage I-II Breast Cancer
- Neoadjuvant Chemotherapy
- Eligible for BCT
  - Randomize
    - No Breast MRI
      - BCT
      - Follow
    - Breast MRI
      - Based on MRI: Candidate for BCT
        - BCT
        - Follow
      - Based on MRI: Not a candidate for BCT
        - Mastectomy

Accrual By Site
Accrual By Month
Follow Up

Please use the headings above to navigate through the different sections of the poster.
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 on the CTSU website
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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Rationale

Trial Endpoints

Study Schema

FAQs

Key Eligibility Criteria

Accrual By Site

Accrual By Month

Follow Up

Accrual data is through 09/30/2019

Please use the headings above to navigate through the different sections of the poster
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Accrual By Month

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Funding Support

Alliance A011104 is funded by the National Institutes of Health through National Cancer Institute grant awards.

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