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.
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
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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)
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

Sample size: 144 patients/arm
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: 279/317
Number of sites: 54

Accrual data is through 02/28/2019
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Rationale
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Follow Up

Please use the headings above to navigate through the different sections of the poster.
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