ACRIN 6688

PHASE II STUDY OF 3'-DEOXY-3'-18F FLUOROTHYMIDINE (FLT) IN INVASIVE BREAST CANCER

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ACRIN 6688: Primary Objective

- Primary Objective: correlate the percentage change in \( \text{SUV}_{60} \) between baseline (FLT-1) and early-therapy (FLT-2) with pathologic complete response to neoadjuvant chemotherapy of the primary tm in pts with locally advanced breast ca
  - Planned 54 eligible pts to yield 49 pts to evaluate primary aim
  - 80% to identify FLT predictive value for early response

- Key secondary aim: correlate FLT uptake with Ki-67 score
Obtain pre-treatment proliferative Indices

Establish Eligibility

• Baseline organ function
• Pathologically confirmed disease
• Determine primary systemic Rx

Obtain post-treatment proliferative Indices

Surgical Resection

• Pathologic response,
• Ki-67, mitotic index, surg. specimens

Obtain post-treatment proliferative Indices

Early therapy Imaging

Chemotherapy cycle 1

• Ki-67, mitotic index on bx sample or re-biopsy (if available)

Chemotherapy last cycle

Baseline Imaging

18FLT PET/CT (FLT-1)

18FLT PET/CT (FLT-2)

18FLT PET/CT (FLT-3)
ACRIN 6688: Participating Sites

- University of Pennsylvania School of Medicine
- Washington Univ Med School
- Thomas Jefferson Univ Hosp
- University of North Carolina
- University of Washington
- Wake Forest University
- Medical Univ of South Carolina
- University of Louisville
- Ochsner Foundation Hospital
- Virginia Commonwealth Univ
- Scottsdale Med Imaging, LTD
- University of Arkansas
- Univ. Southern California
- Radiology Consultants, Inc.
- University of Wisconsin Hosp
- Pennsylvania State/Milton S. Hershey Medical Center
- Morton Plant Mease Health Care, Inc.
- Excel Diag. Imaging Clinics
- Wayne State University
- Mount Sinai Medical Center
- Fox Chase Cancer Center
## Accrual Plot

<table>
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<tr>
<th>Year</th>
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Total accrual: 90 patients

- Evaluable for primary aim analysis: 53
- Dropouts
  - Withdrawal: 8
  - Prior amendment: 5
  - Timing relative to chemo or imaging issue: 26
- Accrual completed: 9/28/12
53 evaluable

- 43 pre and post path reports received
- 8 pre path reports received, post reports outstanding
- 2 pre and post path reports outstanding (1 surgery form received)
Opening sites for a novel tracer takes time
  – Site training is key
Confirming the eligibility with the entire team crucial
Logistics of tracer ordering and delivery is challenging
Tight timing of imaging relative to therapy requires close monitoring
Patent logistics, therapy schedule and therapy related side effects should be considered
Early analysis of accrual patterns (and issues) is key
ACRIN 6688: Summary

- Trial to test proliferation imaging (FLT PET/CT) as measure of early cancer response
- Comparison between imaging changes and pathologic response
- Accrual completed, study completion and analysis ongoing
- Important paradigm as a trial of novel molecular imaging approaches