

ONCOLOGIST FACT SHEET

I-SPY 2 Trial For Locally Advanced Breast Cancer

Now Enrolling
20+ Sites Across America

ClinicalTrials.gov Identifier: NCT01042379

ISPYtrials.org

The I-SPY 2 Trial (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And Molecular Analysis) is a neoadjuvant clinical trial for locally advanced breast cancer designed to test Phase II investigational agents in a curable patient population.



SCREENING ELIGIBILITY

- Patients newly diagnosed with invasive breast cancer, stage 2 or 3, with a tumor 2.5 cm or larger

TREATMENT ELIGIBILITY

- Determined by HR and HER2 status and MammaPrint® score.
- To be eligible for I-SPY 2, the cancer must be one of the following:
 - MammaPrint® High Risk
 - MammaPrint® Low Risk and ER-
 - MammaPrint® Low Risk and Her2+
 - MammaPrint® Low Risk and ER+ are eligible for the Endocrine Optimization Protocol

MammaPrint®: a test to predict risk of breast cancer recurrence

MammaPrint® analyzes the 70 most important genes associated with breast cancer recurrence to classify each patient with breast cancer into “Low Risk” or “High Risk” of developing metastases within 10 years of diagnosis.

WHY CONSIDER THE I-SPY 2 TRIAL?

- The I-SPY 2 Trial’s ground-breaking adaptive, multi-agent design allows up to five investigational drugs (or combinations of agents) to be evaluated in parallel.
- Investigational chemotherapy drugs are evaluated against paclitaxel (+/- pertuzumab & trastuzumab for HER2+) followed by anthracyclines (AC).
- The I-SPY 2 Trial’s adaptive randomization engine assigns a participant to a study arm, including the control arm, giving greater weight to arms that have been successful for the participant’s tumor subtype in the I-SPY 2 Trial.
- The Endocrine Optimization Protocol uses 1:1:1 assignment of investigational agent and combinations. Each arm includes a Selective Estrogen Receptor Degradator (SERD).
- Neoadjuvant therapy in the I-SPY 2 Trial enables serial MRI assessment of tumor response.
- Information on I-SPY 2 Trial’s prior investigational agents can be found at <https://www.ISPYtrials.org/results/past-agents>