Resource Summary Report

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I-SPY 2 TRIAL

RRID:SCR_003713

Type: Tool

Proper Citation

I-SPY 2 TRIAL (RRID:SCR_003713)

Resource Information

URL: http://ispy2.org/

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Description: A collaboration to test an adaptive clinical trial model that would assess the efficacy of a candidate therapeutic earlier than traditional clinical trials, potentially enabling drugs to be developed and approved using fewer patients, less time and fewer resources. This trial focuses on women with newly diagnosed locally advanced breast cancer to test whether adding investigational drugs to standard chemotherapy is better than standard chemotherapy alone. It uses genetic and biological markers from individual patients' tumors to screen several promising new treatments simultaneously and allows doctors to quickly measure the effectiveness of the treatment prior to removing the tumor. The experimental adaptive trial design uses patient outcomes to immediately inform treatment options for subsequent trial participants. The trial has 5 components that differentiate it from conventional clinical trial models. # I-SPY2 uses tissue and imaging biomarkers from individual cancer patients' tumors to determine eligibility, guide/screen promising new treatments and identify which treatments are most effective in specific tumor subtypes. # The trial's adaptive design allows the Team to learn as they go, enabling researchers to use data from patients early in the trial to guide decisions about which treatments might be more useful for patients who enter the trial earlier. I-SPY2 provides a scientific basis for researchers to eliminate ineffective treatments and graduate effective treatments more quickly. # The neoadjuvant treatment approach - in which chemotherapy is given to patients prior to surgery - allow the team to evaluate tumor response with MRI before removal. This approach is safe as treating after surgery, allowing tumors to shrink, and more importantly, it enables critical learning early on about how well treatments work. # The ability for the team to screen multiple drug candidates developed by multiple companies. New agents will be selected and added as those used initially and either graduate to Phase III, or are dropped, based on their efficacy in targeted patients. # The trials informatics system allows data to be collected, verified, and shared in real-time. This allows data to be assessed early and in an

integrated fashion - with an aim to enhance and encourage collaboration

Abbreviations: I-SPY 2, ISPY2, I-SPY2

Synonyms: Investigation of Serial Studies to Predict Your Therapeutic Response With

Imaging And moLecular Analysis 2, ISPY-2 Clinical Trials

Resource Type: clinical trial, portal, data or information resource, consortium, organization

portal

 $\textbf{Keywords:} \ \text{drug, chemotherapy, oncology, female, drug development, biomarker, imaging,} \\$

tissue, mri, paclitaxel, trastuzumab, anthracycline, cyclophosphamide, clinical

Funding: non-profit foundations;

Safeway Foundation;

pharmaceutical companies;

Johnson and Johnson;

Amgen;

Lilly;

Pfizer;

Eisai ;

Genentech;

Quintiles TransNational Corp

Resource Name: I-SPY 2 TRIAL

Resource ID: SCR_003713

Alternate IDs: nlx 157884

Record Creation Time: 20220129T080220+0000

Record Last Update: 20250426T055641+0000

Ratings and Alerts

No rating or validation information has been found for I-SPY 2 TRIAL.

No alerts have been found for I-SPY 2 TRIAL.

Data and Source Information

Source: SciCrunch Registry

Usage and Citation Metrics

We found 4 mentions in open access literature.

Listed below are recent publications. The full list is available at ASWG.

Everett AS, et al. (2018) Postmastectomy Radiation Therapy: Are We Ready to Individualize Radiation? International journal of breast cancer, 2018, 1402824.

Thibault G, et al. (2017) DCE-MRI Texture Features for Early Prediction of Breast Cancer Therapy Response. Tomography (Ann Arbor, Mich.), 3(1), 23.

Tudorica A, et al. (2016) Early Prediction and Evaluation of Breast Cancer Response to Neoadjuvant Chemotherapy Using Quantitative DCE-MRI. Translational oncology, 9(1), 8.

Bielekova B, et al. (2014) How implementation of systems biology into clinical trials accelerates understanding of diseases. Frontiers in neurology, 5, 102.