I-SPY 2 is a phase 2 screening process that attempts to match experimental therapies with specific patient subtypes to improve the success rate of new drugs. I-SPY 2's adaptive randomization was successful in efficiently evaluating 300 patient phase 3 clinical studies within the respective subtype population.

**Eligibility and Methods**

- Trebananib is an angiopoeitin-1/2-neutralizing peptide that inhibits interaction with the Tie2 receptor.

**Dose Delays**

- Dose delay/reduction occurred in 24% of patients in the experimental arm compared to 20% in the control arm and the time to surgery between these arms were comparable.

**Adverse Events**

- Table 2: Adverse Events

**Table 1: Biomarker Subtypes with Overall Prevalence in I-SPY 2 to Date**

- Within-patient longitudinal modeling of MRI volume was used during the trial to predict whether the patient would experience a pCR and improve the efficiency of adaptive treatment assignments.

**Figure 3: Bayesian PCR Probability Distributions: Results**

- Table 2: Adverse Events

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**Conclusions**

- The I-SPY 2 phase 2b screening process aims to match experimental therapies with specific patient subtypes.

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**Table 2: Adverse Events**

- Trebananib was well-tolerated with only minor toxicity observed.

- Although no subtype reached the efficacy threshold, the data suggested there may be a benefit for HER2- (highly correlated with HR+), HR-/HER2- and HR-/HER2+ tumors, which may be explored in future studies.

- The I-SPY 2 standing trial mechanism is effective in combinations that most likely to succeed in phase 3 biomarker-defined patient subsets.