Active Symptom Monitoring and Endocrine Therapy Persistence in Young Women with Breast Cancer

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Treatment with endocrine therapy in combination with ovarian function suppression (OFS) for 5 years improves disease-free survival in premenopausal women with hormone receptor positive breast cancer compared to tamoxifen alone. However, there is a high rate of early treatment discontinuation, which can increase breast cancer recurrence and mortality. Most patients who discontinue treatment prematurely do so because of bothersome toxicities and decreased quality of life (QOL). Therefore, approaches are needed to improve symptom management in young women at high risk of breast cancer recurrence.

Use of patient reported outcomes (PRO) improves patient-provider communication and patient satisfaction. In advanced cancer, active symptom monitoring (ASM) between clinic visits with a web-based tool improves health-related QOL and increases overall survival. However, there are limited if any data to support the use of ASM with PROs to impact disease outcomes in early stage cancer.

The objectives of this R01 are to evaluate the effectiveness of ASM on endocrine therapy discontinuation, and to identify factors associated with benefit from this management approach. We hypothesize that early identification of toxicity will change the symptom experience of patients, leading to increased persistence with therapy. Therefore, we are applying the ASM methodology to a diverse, multiethnic cohort of premenopausal women with newly diagnosed high risk, early stage breast cancer. Our study is leveraging the resources of the NCI Community Oncology Research Program (NCORP) and the SWOG Cancer Research Network. We are enrolling 540 patients initiating treatment with endocrine therapy plus OFS and randomizing them to proactive, web-based symptom assessment plus patient education versus patient education alone. The clinical trial was activated January 17, 2023, and the first patient enrolled at the end of March. To date, 87 participants have been enrolled across the United States and Latin America.

The following Specific Aims are being addressed: (1) to investigate the impact of ASM on 18-month persistence with endocrine therapy, (2) to examine the effect of ASM on severity of key treatment-emergent symptoms in premenopausal women with early stage breast cancer, and (3) to develop a risk prediction model to identify patients at increased risk of ET nonpersistence who are likely to benefit from ASM. Through this series of Aims we expect to demonstrate the effectiveness of ASM on persistence with and tolerance of endocrine therapy in a cohort of young women with breast cancer. In addition, we expect to obtain new knowledge that will provide important preliminary data to support future interventional studies targeting reasons for nonpersistence with endocrine therapy. Improving persistence with endocrine therapy and reducing treatment-associated toxicity will lead to improved disease outcomes and quality of life for young breast cancer survivors.