CTSU E1Z11: A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)

Fast Facts

Selection of Patients:

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday four weeks later would be considered Day 28.

1. Age ≥ 18 years.
2. Patients must be female and post-menopausal. Post-menopausal will be defined as women meeting any of the following criteria:
   - ≥ 60 years of age; or
   - < 60 years of age and amenorrheic for ≥ 12 months prior to day 1 if uterus/ovaries are intact; or
   - < 60 years of age, and the last menstrual period 6-12 months prior to day 1, if intact uterus/ovaries and meets biochemical criteria for menopause (FSH and estradiol within institutional standard for postmenopausal status); or
   - < 60 years of age, without a uterus, and meets biochemical criteria for menopause (FSH and estradiol within institutional standards for postmenopausal status); or
   - < 60 years of age and history of bilateral oophorectomy. Surgery must have been completed at least 4 weeks prior to day 1; or
   - Prior radiation castration with amenorrhea for at least 6 months.

   NOTE: Use of LHRH agonists (e.g., leuprolide or goserelin) is not allowed
3. Patients must have estrogen and/or progesterone receptor positive histologically confirmed Stage I-III adenocarcinoma of the breast.
4. Patients must have completed recommended local therapy and adjuvant chemotherapy for breast cancer.
5. Patients must have completed planned local therapy (i.e., definitive surgery and radiation therapy) and adjuvant chemotherapy for breast cancer prior to registration. In addition, any prior local therapy and adjuvant chemotherapy should be completed prior to participant completion of baseline PRO instruments (i.e., HAQ, PROMIS Physical Function, FACT Breast and ES, etc.) and collection of optional blood for banking for future research.

   NOTE: Concomitant treatment with ongoing trastuzumab (Herceptin®) or other targeted/biologic agents is allowed. Concomitant treatment with any other type of chemotherapy or hormonal therapy is not allowed.
6. Patients must not have received prior AI therapy with exemestane, letrozole, or anastrozole as preoperative/adjuvant therapy or for prevention of breast cancer. Prior tamoxifen is allowed.

7. Plan to treat with anastrozole for at least 12 months.
8. ECOG performance status between 0-2.
9. Patients must not have prior history of ovarian, endometrial, or fallopian tube carcinoma, and/or primary peritoneal carcinomatosis.
10. Patients must be disease-free of other prior invasive malignancies for ≥ 5 years with the exception of curatively-treated basal cell or squamos cell carcinoma of the skin or carcinoma in situ of the cervix. Prior early stage breast cancers are also allowed as long as prior treatment did not include aromatase inhibitors.
11. Patients must not be currently taking (or have taken in the past 6 months) ongoing, daily analgesic medication for active, chronic conditions (i.e., rheumatoid arthritis, carpal tunnel syndrome, tenosynovitis, systemic lupus erythematosus, gout, fibromyalgia, or severe osteoarthritis involving the hands, wrists, hips, knees, feet or ankles). (Note: patients taking daily low dose aspirin are allowed to participate in this trial.)
12. Patients must not have a prior history of deep vein thrombosis (DVT) or pulmonary embolism in the past 5 years.
13. Patients must have worst pain rated as less than 3 out of 10 on the following question (i.e., a pain score of 0,1,2, or 3): "In the past week, how much pain have you had on a scale of 0 to 10, where 0 equals no pain and 10 means the worst pain you can imagine."
    NOTE: This question regarding patient's pain should be completed within one week prior to registration. This pain item may be completed orally prior to consent up to 7 days prior to registration. It is not necessary to complete this pain item via the PROMIS website.
14. Patients must have adequate hepatic, hematologic and renal functioning to be able to be administered anastrozole at the discretion of the treating physician.

For each patient, the eligibility checklist (section 3.0) must be photocopied, completed and maintained in the patient's chart.

Pre-Study Parameters:

1. History and PE to include exam of the joints, ECOG PS and vitals
2. Eight (8) Patient Reported Outcome (PRO) measures per section 6.0
3. Mandatory and optional biological sample submissions at baseline and multiple time-points per section 10.0