Elacestrant Versus Standard Endocrine Therapy in Women and Men With Node-positive, Estrogen Receptor-positive, HER2-negative, Early Breast Cancer With High Risk of Recurrence-A Global, Multicenter, Randomized, Open-label Phase 3 Study

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- ER-positive, HER2-negative breast cancer without evidence of recurrence or distant metastases - considered to be at high risk when cancer was initially diagnoses - have received at least 24 months but not more than 60 months of endocrine therapy - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- inflammatory breast cancer - history of prior invasive breast cancer - history of another cancer in the past 3 years - have had more than a 6-month continuous interruption of endocrine therapy or who are off currently off endocrine therapy more than 6 months - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Drug: Anastrozole, Drug: Elacestrant, Drug: Exemestane, Drug: Letrozole, Drug: Tamoxifen
Conditions:
Cancer
Keywords:
Breast Cancer

More Information

Description: The goal of this study is to evaluate the effectiveness of elacestrant compared to standard endocrine therapy in participants with node-positive, Estrogen Receptor-positive (ER+), Human Epidermal Growth Factor-2 negative (HER2-) early breast cancer with high risk of recurrence.
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Phase: PHASE3
IRB Number: MMCORC097