OptimICE-PCR: De-Escalation of Therapy in Early-Stage TNBC Patients Who Achieve pCR After Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- at least 18 years old - able to walk and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - no cancer remaining in the breast or lymph nodes after the completion of neoadjuvant therapy (complete response) - Estrogen (ER) and progesterone (PR) no more than 10% and HER2-negative - if cancer was present in both breasts, participation in the study is permitted as long as the eligibility criteria are met for both tumors/breasts - must have received neoadjuvant chemotherapy in combination with pembrolizumab for a minimum of 6 cycles - not pregnant and not nursing - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- stage IV (metastatic) breast cancer - known active liver disease -medical conditions that require chronic systemic steroids (>10 mg prednisone daily or equivalent) or any other form of immunosuppressive medications and has required such therapy in the last two years

Conditions & Interventions

Conditions:
Cancer
Keywords:
Breast Cancer, TNBC, Triple Negative Breast Cancer, Clinics and Surgery Center (CSC)

More Information

Description: We are doing this study because we want to find out if observation is as good as the usual care for breast cancer. The usual approach for patients with early-stage triple-negative breast cancer (TNBC) who receive preoperative chemotherapy plus pembrolizumab is to continue to receive FDA-approved pembrolizumab for up to 27 weeks after surgery. Participants will either get pembrolizumab for up to 27 weeks, or will not receive any treatment and will be observed for up to 27 weeks. We will continue to follow participants every 6 months for 5 years and watch for side effects or cancer coming back. After that, participants will be checked every year for a total of 10 years after the study.
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IRB Number: STUDY00021547