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:

- walking and able to do all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours - diagnosis of Triple Negative Breast Cancer (TNBC) without any remaining disease after neoadjuvant chemotherapy with pembrolizumab for at least 6 cycles - no more than 12 weeks between surgery and starting the trial - see link to clinicaltrails.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- stage IV (metastatic) breast cancer - women who are pregnant or breast feeding - history of any prior invasive breast cancer in either breast - 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

Interventions:
Procedure: Biopsy, Procedure: Biospecimen Collection, Other: Patient Observation, Biological: Pembrolizumab, Other: Quality-of-Life Assessment, Other: Questionnaire Administration
Conditions:
Cancer
Keywords:
TNBC, Triple Negative Breast Cancer

More Information

Description: This trial compares the effect of pembrolizumab to observation for the treatment of patients with early-stage triple-negative breast cancer who had a complete response after preoperative chemotherapy in combination with pembrolizumab. Immunotherapy with monoclonal antibodies, such as pembrolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. This trial may help researchers determine if observation will result in the same risk of cancer coming back as pembrolizumab after surgery.
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Phase: PHASE3
IRB Number: MMCORC077