Shorter Chemo-Immunotherapy Without Anthracycline Drugs for Early-Stage Triple Negative Breast Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participants must have histologically confirmed estrogen receptor (ER)-negative, progesterone receptor (PR)-negative, and HER2-negative breast cancer (TNBC) defined as ER \< 5%, PR \< 5%, and HER2 negative (per 2020 American Society of Clinical Oncology \[ASCO\] College of American Pathologists \[CAP\] guidelines) * NOTE: Participants with weakly ER or PR positive disease, defined as ER and/or PR between 1-4% by immunohistochemistry, are eligible if adjuvant endocrine therapy is not recommended/planned by the treating physician * Participants must have American Joint Committee on Cancer (AJCC) 8 anatomic tumor clinical stage either * T2-T4, N0, M0 or * T1-T3, N1-2, M0 * Note: All participants with clinically suspicious nodes must undergo core needle biopsy or fine needle biopsy per standard clinical practice to pathologically confirm nodal status * Participants must have breast and axillary imaging with mammogram and/or ultrasound and/or magnetic resonance imaging (MRI) within 49 days prior to randomization * Note: Participants with bilateral invasive breast cancer are eligible if both breast cancers are ER-negative, PR-negative, and HER2-negative provided they meet the other eligibility criteria * Participants must not have T4/N+, any N3, or inflammatory breast cancer * Participants must not have metastatic disease (M1) * Participants must not have received prior systemic therapy or radiation therapy with curative intent for the current breast cancer * Participants must not have had previous definitive ipsilateral breast surgery for the current breast cancer * Participants must not have current or anticipated use of other investigational agents while participating in this study * Participants must not have history of allergic reactions attributed to compounds of similar chemical or biologic composition as study agents * Participants must not have severe hypersensitivity (\>= grade 3) to pembrolizumab or any of its excipients * Participants must not have received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g. CTLA-4, OX-40, CD137) * Participants must not be currently participating in or have participated in a study of an investigational agent or used an investigational device within 28 days prior to randomization * Participants must be \>= 18 years old * Participants must have Zubrod performance status of 0-2 * Participants with evidence of peripheral neuropathy must have it at =\< grade 1, by Common Terminology Criteria for Adverse Events (CTCAE) version (v.) 5.0, within 28 days prior to randomization * Participants must have a complete medical history and physical exam within 28 days prior to randomization * Hemoglobin \>= 9.0 g/dL or \>= 5.6 mol/L (within 28 days prior to randomization) * (Criteria must be met without erythropoietin dependency and without packed red blood cell transfusion within last 2 weeks) * Leukocytes \>= 3 x 10\^3/uL (within 28 days prior to randomization) * Absolute neutrophil count \>= 1.5 x 10\^3/uL (within 28 days prior to randomization) * Platelets \>= 100 x 10\^3/uL (within 28 days prior to randomization) * Total bilirubin =\< 1.5 x institutional upper limit of normal (IULN), OR direct bilirubin =\< IULN for participants with total bilirubin \> 1.5 x IULN (unless history of Gilbert's disease. Participants with history of Gilbert's disease must have total bilirubin =\< 5 x institutional IULN) (within 28 days prior to randomization) * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) =\< 3 x institutional upper limit of normal (ULN) (within 28 days prior to randomization) * Participants must have a serum creatinine =\< the IULN OR calculated creatinine clearance \>= 50 mL/min/1.73m\^2 using the following Cockcroft-Gault Formula. This specimen must have been drawn and processed within 28 days prior to registration * Participants must have adequate cardiac function. Participants must have left ventricular ejection fraction \>= 50% as assessed by either echocardiography (ECHO) or multigated acquisition scan (MUGA) assessed within 28 days prior to registration. Participants with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, must have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification and must be class 2B or better * Participants with known human immunodeficiency virus (HIV)-infection must be on effective anti-retroviral therapy at randomization and have undetectable viral load test on the most recent test results obtained within 6 months prior to randomization * Participants with evidence of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load while on suppressive therapy on the most recent test results obtained within 6 months prior to randomization, if indicated * Note: No testing for Hepatitis B is required unless mandated by local health authority * Participants with a history of hepatitis C virus (HCV) infection must have been treated and cured. Participants currently being treated for HCV infection must have undetectable HCV viral load test on the most recent test results obtained within 6 months prior to randomization, if indicated * Note: No testing for hepatitis C is required unless mandated by local health authority * Participants with history of diabetes must not have uncontrolled diabetes in the opinion of the treating investigator * Participants must not have uncontrolled hypertension in the opinion of the treating investigator * Participants must not have had a major surgery within 14 days prior to randomization. Participants must have fully recovered from the effects of prior major surgery in the opinion of the treating investigator * Participants must not have severe or active infections within 14 days prior to Randomization, including but not limited to hospitalization for infection, bacteremia, or severe pneumonia * Participants must not have a diagnosis of immunodeficiency and be receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to randomization * Participants must not have active autoimmune disease that has required systemic treatment in 2 years prior to randomization (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment * Participants must not have a history of (non-infectious) pneumonitis that required steroids, or has current (non-infectious) pneumonitis * Participants must not have received a live vaccine within 30 days prior to randomization. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster (chicken pox), yellow fever, rabies, Bacillus Calmette-Guerin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines (e.g., FluMist \[registered trademark\]) are live attenuated vaccines and are not allowed * Participants must not have a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) has the potential to interfere with the safety or efficacy assessment of the treatment regimen * Participants must not be pregnant or nursing. Individuals who are of reproductive potential must have agreed to use an effective contraceptive method with details provided as a part of the consent process. A person who has had menses at any time in the preceding 12 consecutive months or who has semen likely to contain sperm is considered to be of "reproductive potential." In addition to routine contraceptive methods, "effective contraception" also includes refraining from sexual activity that might result in pregnancy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) including hysterectomy, bilateral oophorectomy, bilateral tubal ligation/occlusion, and vasectomy with testing showing no sperm in the semen * Participants must have one (1) physical 4-5-micron single hematoxylin and eosin (H\&E) slide from the archival pretreatment diagnostic biopsy available for submission * Participants must be offered the opportunity to participate in specimen banking. With participant consent, specimens must be collected and submitted via the Southwest Oncology Group (SWOG) Specimen Tracking System * Participants who can complete questionnaires in English, Spanish, or French must be offered the opportunity to participate in the Patient-Reported Outcome study * NOTE: As a part of the Oncology Patient Enrollment Network (OPEN) registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system * Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines * For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and Central Institutional Review Board (CIRB) regulations * As part of the registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system

Conditions & Interventions

Interventions:

Interventions:
PROCEDURE: Biospecimen Collection, DRUG: Carboplatin, DRUG: Cyclophosphamide, DRUG: Docetaxel, DRUG: Doxorubicin, DRUG: Paclitaxel, BIOLOGICAL: Pembrolizumab, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, PROCEDURE: Surgical Procedure
Conditions:
Anatomic Stage I Breast Cancer AJCC v8, Anatomic Stage II Breast Cancer AJCC v8, Anatomic Stage IIIA Breast Cancer AJCC v8, Anatomic Stage IIIB Breast Cancer AJCC v8, Early Stage Triple-Negative Breast Carcinoma

More Information

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