Measuring if Immunotherapy Plus Chemotherapy is Better Than Chemotherapy Alone for Patients With Aggressive Poorly Differentiated Sarcomas

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patient must be \>= 18 years of age * Patient must have a confirmed histopathologic diagnosis of dedifferentiated liposarcoma (DDLPS), undifferentiated pleomorphic sarcoma (UPS) or a related poorly differentiated sarcoma. Because UPS can sometimes exist in a spectrum among related diagnoses, the following additional diagnostic will be allowed, but not limited to: * Pleomorphic sarcoma with inflammation or with limited areas of differentiation * Pleomorphic sarcoma with giant cells * Malignant fibrous histiocytoma (including storiform-pleomorphic and inflammatory subtypes) * Myxofibrosarcoma * Poorly differentiated sarcoma not otherwise specified (NOS) * Undifferentiated spindle cell sarcoma * Poorly differentiated spindle cell sarcoma NOS Any of these subtypes may have areas of focal myogenic differentiation * Patient must have metastatic or unresectable sarcoma * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used. All patients of childbearing potential must have a blood test or urine study within 14 days prior to randomization to rule out pregnancy. A patient of childbearing potential is defined as anyone, regardless of whether they have undergone tubal ligation, who meets the following criteria: * Has achieved menarche at some point * Has not undergone a hysterectomy or bilateral oophorectomy; or * Has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patient must not expect to conceive or father children by using an accepted and effective method(s) of contraception or by abstaining from sexual intercourse for the duration of their participation in the study. Contraception measures must continue for 6 months after the last dose of doxorubicin for patients of child bearing potential and for 3 months after the last dose of doxorubicin for male patients with partners of child bearing potential. Males with pregnant partners should use condoms during doxorubicin treatment and for at least 10 days after the last dose of doxorubicin. Contraception measures must also continue for 4 months after the last dose of pembrolizumab for patients of child bearing potential * Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible * Patient must have a left ventricular ejection fraction (LVEF) \> 50% by either MUGA scan or echocardiogram obtained within 28 days prior to randomization * Absolute neutrophil count (ANC) ≥ 1,500 cells/uL (must be obtained ≤ 7 days prior to protocol randomization) * Platelets ≥ 75,000 cells/uL (must be obtained ≤ 7 days prior to protocol randomization) * Total bilirubin \< 1.2 mg/dL (must be obtained ≤ 7 days prior to protocol randomization) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase \[SGPT\]) ≤ 3.0 × institutional upper limit of normal (ULN) (must be obtained ≤ 7 days prior to protocol randomization) * Creatinine clearance ≥ 30 mL/min according to the Cockcroft-Gault formula (must be obtained ≤ 7 days prior to protocol randomization) * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of randomization are eligible for this trial * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Patients with treated brain metastases are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression * Patients with new or progressive brain metastases (active brain metastases) or leptomeningeal disease are eligible if the treating physician determines that immediate CNS specific treatment is not required and is unlikely to be required during the first cycle of therapy * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * Patient must not have a history of or active interstitial lung disease * Patient must have measurable disease. Baseline imaging must include a chest computed tomography (CT). Imaging should be inclusive of all measurable and non-measurable disease and must be obtained within 28 days prior to randomization. Imaging must be available for uploading to Transfer of Images and Data (TRIAD) * NOTE: CT with (w/) contrast preferred, chest CT without contrast is acceptable, CT portion of positron emission tomography (PET) may be acceptable. Magnetic resonance imaging (MRI) is acceptable for measuring other sites of disease * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status 0-1 * Patient must not have had prior treatment with an anthracycline * Patient must not have a diagnosis of clinically significant immunodeficiency or an autoimmune disorder requiring the patient to use systemic steroid chronically, or systemic steroids within 7 days prior to randomization * Patient must not have a known history of active TB (Bacillus Tuberculosis) * Patient must not have a known hypersensitivity to doxorubicin or pembrolizumab or any of their excipients * Patients who have received prior chemotherapy, targeted small molecule therapy or radiation therapy must have recovered from the prior therapy at the time of randomization * Patient must have recovered adequately from any prior major surgery prior to randomization * Patient must not have had prior pericardial or mediastinal radiation * Patient must not have received prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2 or anti-CTLA4 agent * Patient must not have an autoimmune or other disease that requires the use of daily corticosteroids of \> 10 mg of prednisone (or equivalent). Patients who are on an active steroid taper at the time of randomization must finish prior to beginning study treatment. Patients who require inhaled or topical steroids are eligible

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Diagnostic Imaging Testing, DRUG: Doxorubicin, PROCEDURE: Echocardiography Test, PROCEDURE: Multigated Acquisition Scan, BIOLOGICAL: Pembrolizumab

Conditions:

Metastatic Dedifferentiated Liposarcoma, Metastatic Undifferentiated Pleomorphic Sarcoma, Stage III Soft Tissue Sarcoma of the Trunk and Extremities AJCC v8, Stage IV Soft Tissue Sarcoma of the Trunk and Extremities AJCC v8, Unresectable Dedifferentiated Liposarcoma, Unresectable Undifferentiated Pleomorphic Sarcoma

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06422806

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