Effects of Dexrazoxane Hydrochloride on Biomarkers Associated With Cardiomyopathy and Heart Failure After Cancer Treatment

Status: RECRUITING

Eligibility Criteria

Age: Not specified

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Study Strata I, II, and III are closed for further patient entry as of March 31, 2021. The study remains open for existing medical record submission of Stratum IV * STRATUM I AND STRATUM II: LEUKEMIA AND LYMPHOMA SURVIVORS * Previously enrolled leukemia and lymphoma survivors, randomized to + or

•DRZ on P9404, P9425, P9426, or DFCI 95-01 (high-risk patients only) * STRATUM I: Alive and in continuous first complete remission from their original cancer (leukemia/lymphoblastic lymphoma \[P9404, high-risk DFCI 95-01\] or Hodgkin lymphoma \[P9425/P9426\]) * STRATUM I: Did not have progressive disease or induction failure requiring off-protocol therapy including hematopoietic cell transplantation * STRATUM I: Must not have been diagnosed with any subsequent malignancy that required additional cardiotoxic therapies (i.e., radiotherapy to the chest \[also includes fields directed towards the neck, upper abdomen, or spine\], or additional anthracyclines or anthraquinones); patients with history of subsequent malignancy that did not require such therapies remain eligible * STRATUM I: All patients and/or their parents or legal guardians must sign a written informed consent * STRATUM II: Among leukemia and lymphoma patients randomized to + or

•DRZ on P9404, P9425, P9426, and DFCI 95-01 (high risk patients only) who have relapsed or have experienced a subsequent malignancy that precludes eligibility since their original diagnosis, the study committee will review the available data (both from Children's Oncology Group's \[COG?s\] Statistics and Data Center \[SDC\] and the participating institution) to determine if individual patients are to be selected for Stratum 2; in recognition that local institutions sometimes have more updated relapse/subsequent cancer data than SDC, in cases where local data is more updated, local data will be used preferentially; the study will petition the Institutional Review Board (IRB) specifically for a waiver of consent to include any relapse and subsequent cancer data obtained from existing records for analysis of the secondary aims; patients selected for Stratum 2 will be those for whom late relapse or subsequent cancer is reported but who lack clear confirmation in existing records (either at SDC or at the local institution) * STRATUM II: Alive, but have experienced relapse of their original cancer and/or have developed a subsequent cancer (other than non-melanomatous skin cancer) since their original diagnosis * STRATUM II: All patients and/or their parents or legal guardians must sign a written informed consent * STRATUM III: OSTEOSARCOMA SURVIVORS * Previously enrolled osteosarcoma survivors treated on P9754 who are alive and able (themselves and/or parents/legal guardian) to provide written informed consent; note that relapse and subsequent malignancy are not exclusion criteria for P9754 survivors * Comparison subjects for P9754 survivors will be eligible to be enrolled from any ALTE11C2 participating COG site (even if that institution did not participate on P9754), according to the following criteria: * Newly diagnosed, previously untreated biopsy-proven moderate or high grade osteosarcoma without metastasis; patients with low grade osteosarcoma, parosteal or periosteal sarcoma are ineligible * \< 31 years of age at time of initial osteosarcoma diagnosis * Diagnosis occurred between January 1, 1999 through December 31, 2002; duration of therapy can extend beyond 2002 * No evidence of poor or low cardiac function at time of initial osteosarcoma diagnosis; if reports from the time are available: shortening fraction \>= 28% by echocardiogram and within the institutional normative range for age, or radionuclide angiogram ejection fraction \>= 50%; if imaging reports from the time are no longer available, there must be no documentation within available medical records that suggest poor or low cardiac function at time of diagnosis * Comparison subject must have institutional records (e.g., clinic note, treatment summary, chemotherapy roadmap) documenting lifetime receipt of 450 to 600 mg/m\^2 of doxorubicin (doses within 10% are acceptable); this includes initial therapy as well as any subsequent therapy for relapse or second cancer, if relevant; as such, comparison subjects who have had osteosarcoma relapse or subsequent malignancies remain eligible so long as they meet all other eligibility criteria * No anthracycline or anthraquinone aside from doxorubicin was ever given as part of initial or subsequent therapies * No exposure to DRZ at any point in time * All patients and/or their parents or legal guardians must sign a written informed consent * STRATUM IV: CARDIOMYOPATHY CASES, NOT OTHERWISE ELIGIBLE FOR STRATUMS 1, 2, AND 3 * Individuals diagnosed with cancer prior to age 21 years, who required treatment with chemotherapy and/or radiotherapy, achieved initial remission, and remained alive after completing anti-cancer-therapy for at least 1 year * Must have screening echocardiograms for heart function as part of cancer therapy and off-therapy evaluations available (Digital Imaging and Communications in Medicine \[DICOM\] format). Images from Video Home System (VHS) tapes and reports only (without images) are not suitable * Cannot have a known history of congenital heart disease (patent foramen ovale remain eligible) or underlying genetic syndrome associated with abnormal cardiovascular development or health (e.g., down syndrome) * Based on echocardiography, must have either left ventricular fractional shortening =\< 28.0% or ejection fraction =\< 50.0% on at least two occasions, with at least one of these measurements occurring after cancer therapy completion and be in the absence of sepsis or any uncontrolled infection * If the fractional shortening or ejection fraction criteria is only met on one occasion, this must be after cancer therapy completion, be in the absence of sepsis or any uncontrolled infection, and the patient must have subsequently started on chronic medical therapy for cardiomyopathy (e.g., beta-blocker, angiotensin-converting enzyme \[ACE\]-inhibitor, angiotensin receptor blocker) lasting at least 6 months * For all participants (stratums 1, 2, 3, and 4), all institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

Conditions & Interventions

Interventions:

OTHER: Assessment of Therapy Complications, OTHER: Laboratory Biomarker Analysis, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration

Conditions:

Hodgkin Lymphoma in Remission, Leukemia in Remission, Lymphoblastic Lymphoma, Osteosarcoma, Recurrent Leukemia, Recurrent Lymphoma, Recurrent Malignant Neoplasm

More Information

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Phase: N/A

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