Chemotherapy for the Treatment of Patients With Newly Diagnosed Very Low-Risk and Low Risk Fusion Negative Rhabdomyosarcoma

Status: RECRUITING

Eligibility Criteria

Age: Up to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* All patients must be enrolled on APEC14B1 (NCT02402244) and consented to the Molecular Characterization Initiative (Part A) prior to enrollment and treatment on ARST2032 (this trial). * Patients must be =\< 21 years at the time of enrollment. * Patients must have newly diagnosed embryonal rhabdomyosarcoma (ERMS), spindle cell/sclerosing RMS, or FOXO1 fusion negative alveolar rhabdomyosarcoma (ARMS) (institutional FOXO1 fusion results are acceptable). RMS types included under ERMS include those classified in the 1995 International Classification of Rhabdomyosarcoma (ICR) as ERMS (classic, spindle cell, and botryoid variants), which are reclassified in the 2020 World Health Organization (WHO) classification as ERMS (classic, dense and botryoid variants) and spindle cell/sclerosing RMS (encompassing the historical spindle cell ERMS variant and the newly recognized sclerosing RMS variant). Enrollment in APEC14B1 is required for all patients. * All patients will be evaluated for stage and clinical group. Note that clinical group designation assigned at the time of enrollment on study remains unchanged regardless of any second-look operation that may be performed. * Patients will be eligible for the very low-risk stratum (Regimen VA) if they have Stage 1, CG I disease. * Patients will be eligible for the low-risk stratum (Regimen VAC/VA) if they have Stage 1, CG II disease, Stage 2, CG I or II disease, or Stage 1, CG III (orbit only) disease. * Paratesticular Tumors: Staging ipsilateral retroperitoneal lymph node sampling (SIRLNS) is required for all patients \>= 10 years of age with paratesticular tumors who do not have gross nodal involvement on imaging. * Extremity Tumors: Regional lymph node sampling is required for histologic evaluation in patients with extremity tumors. * Clinically or radiographically enlarged nodes must be sampled for histologic evaluation. * Patients must have a Lansky (for patients =\< 16 years of age) or Karnofsky (for patients \> 16 years of age) performance status score of \>= 50. Patients who are unable to walk because of paralysis, but who are up in a wheelchair, will be considered ambulatory for the purpose of assessing performance score. * Peripheral absolute neutrophil count (ANC) \>= 750/uL (within 7 days prior to enrollment). * Platelet count \>= 75,000/uL (transfusion independent) (within 7 days prior to enrollment). * Creatinine clearance or radioisotope glomerular filtration rate (GFR) \>= 70 mL/min/1.73 m\^2 or a serum creatinine (within 7 days prior to enrollment) based on age/gender as follows: * Age: 1 month to \< 6 months; Maximum serum creatinine (mg/dL): 0.4 (male) : 0.4 (female) * Age: 6 months to \< 1 year; Maximum serum creatinine (mg/dL): 0.5 (male) : 0.5 (female) * Age: 1 to \< 2 years; Maximum serum creatinine (mg/dL): 0.6 (male) : 0.6 (female) * Age: 2 to \< 6 years; Maximum serum creatinine (mg/dL): 0.8 (male) : 0.8 (female) * Age: 6 to \< 10 years; Maximum serum creatinine (mg/dL): 1 (male) : 1 (female) * Age: 10 to \< 13 years; Maximum serum creatinine (mg/dL): 1.2 (male) : 1.2 (female) * Age: 13 to \< 16 years; Maximum serum creatinine (mg/dL): 1.5 (male) : 1.4 (female) * Age \>= 16 years; Maximum serum creatinine (mg/dL): 1.7 (male) : 1.4 (female) * Total bilirubin =\< 1.5 x upper limit of normal (ULN) for age (within 7 days prior to enrollment), and * If there is evidence of biliary obstruction by the tumor, then the total bilirubin must be \< 3 x ULN for age. * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L. * Serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase \[ALT\]) =\< 135 U/L * If there is evidence of biliary obstruction by the tumor, then the total bilirubin must be \< 3 x ULN for age * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L * All patients and/or their parents or legal guardians must sign a written informed consent. * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met.

Exclusion Criteria:

* Patients who have received prior chemotherapy and/or radiation therapy for cancer prior to enrollment. Surgical resection alone of previous cancer(s) is permitted. * Patients who have received chemotherapy or radiation for non-malignant conditions (e.g., autoimmune diseases) are eligible. Patients must discontinue chemotherapy for non-malignant conditions prior to starting protocol therapy. * Vincristine is sensitive substrate of the CYP450 3A4 isozyme. Patients must not have received drugs that are moderate to strong CYP3A4 inhibitors and inducers within 7 days prior to study enrollment. * Patients unable to undergo radiation therapy, if necessary, as specified in the protocol. * Evidence of uncontrolled infection. * Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential. * Lactating females who plan to breastfeed their infants. * Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation.

Conditions & Interventions

Interventions:
PROCEDURE: Biopsy, PROCEDURE: Bone Scan, PROCEDURE: Computed Tomography, DRUG: Cyclophosphamide, BIOLOGICAL: Dactinomycin, PROCEDURE: Magnetic Resonance Elastography, PROCEDURE: Positron Emission Tomography, RADIATION: Radiation Therapy, DRUG: Vincristine

Conditions:
Embryonal Rhabdomyosarcoma, Fusion-Negative Alveolar Rhabdomyosarcoma, Spindle Cell/Sclerosing Rhabdomyosarcoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT05304585
