COG AGCT1531 - A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors

Status: Recruiting

Eligibility Criteria

Sex: All
Age: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• There is no age limit for the low risk stratum (stage I ovarian immature teratoma and stage I non-seminoma or seminoma malignant GCT [all sites])

• Standard risk 1: Patient must be < 11 years of age at enrollment

• Standard risk 2: Patients must be >= 11 and < 25 years of age at enrollment

• Patients enrolling on one of the low risk arms must be newly diagnosed with a stage I germ cell tumor; for the standard risk arms, patients must be newly diagnosed with metastatic germ cell tumor (stage II or higher); histologic confirmation of a primary extracranial germ cell tumor in any of the categories outlined below is required of all patients at enrollment except for those who were initially diagnosed with stage I non-seminoma malignant GCT and later recur during observation post surgery off study; for these patients, if elevated tumor markers rise to > 5 x upper limit of normal (ULN) on at least 2 measurements taken at least 1 week apart, a diagnostic biopsy is not required for enrollment

• Low risk stage I immature teratoma (IT); site: ovarian; stage: Children's Oncology Group (COG) stage I, Federation of Gynecology and Obstetrics (FIGO) stage IA and IB; grade: 2 or 3; histology: pure immature teratoma (may contain microscopic foci of yolk sac tumor), mixed immature and mature teratoma, (no pathological evidence of MGCT); tumor markers: alpha-FP =< 1,000 ng/mL, beta-HCG institutional normal; all ages

• Low risk stage I non-seminoma MGCT; site: ovarian, testicular, or extragonadal; stage: COG stage I, FIGO stage IA and IB, American Joint Committee on Cancer (AJCC) testicular stage IA, IB and IS; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma (pure or mixed); all ages

• Low risk stage I seminoma-MGCT; site: testicular; stage: COG stage I; AJCC testicular stage IA IB, and IS; histology: must contain at least one of the following: may contain immature/mature teratoma; may NOT contain yolk sac tumor, embryonal carcinoma, or choriocarcinoma; all ages

• Standard risk 1 (SR1); site: ovarian, testicular, or extragonadal; stage: COG stage II-IV, FIGO stage IC, FIGO stage II-IV (International Germ Cell Consensus Classification [IGCCC] criteria DO NOT apply); histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma; age (years) < 11

• Standard risk 2 (SR2)

• Site: ovarian; stage: COG stage II and III, FIGO stage IC, II and III; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma; age (years) >= 11 and < 25

• Site: testicular; stage: COG stage II-IV, AJCC stage II, III, IGCCC good risk; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma; tumor markers: must be IGCCC good risk; post op: alpha-FP < 1,000 ng/mL, beta-HCG < 5,000 IU/mL and lactate dehydrogenase (LDH) < 3.0 x normal; age (years) >= 11 and < 25

• Site: extragonadal; stage: COG stage II; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma; age (years) >= 11 and < 25

• Notes:

• IGCCC criteria only apply to SR2 patients with a testicular primary tumor

• Use post-op tumor marker levels to determine IGCCC risk group

• Stage 1 seminoma patients are not eligible for the standard risk arms of the study

• For the low risk stage I non-seminoma MGCT and the standard risk arms, components of yolk sac tumor, embryonal carcinoma, or choriocarcinoma can be mixed with other forms of GCT, such as seminoma or mature or immature teratoma; if yolk sac tumor is the only malignant component present, then it must be deemed by the pathologist to be greater than a "microscopic component" of yolk sac tumor

• Patients must have a performance status corresponding to Eastern Cooperative Oncology Group (ECOG) scores of 0, 1, 2 or 3; use Karnofsky for patients > 16 years of age and Lansky for patients =< 16 years of age

• Organ function requirements apply ONLY to patients who will receive chemotherapy (SR1 and SR2 patients)

• Adequate renal function defined as:

• Creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 mL/min/1.73 m^2 OR

• A serum creatinine based on age/gender as follows: (mg/dL)

• 1 month to < 6 months male: 0.4 female: 0.4

• 6 months to < 1 year male: 0.5 female: 0.5

• 1 to < 2 years male: 0.6 female: 0.6

• 2 to < 6 years male: 0.8 female: 0.8

• 6 to < 10 years male: 1 female: 1

• 10 to < 13 years male: 1.2 female: 1.2

• 13 to < 16 years: male: 1.5 female: 1.4

• >= 16 years male: 1.7 female: 1.4

• Total bilirubin =< 1.5 x upper limit of normal (ULN) for age

• Serum glutamic-oxaloacetic transaminase (SGOT) (aspartate aminotransferase [AST]) or serum glutamate pyruvate transaminase (SGPT) (alanine aminotransferase [ALT]) < 2.5 x upper limit of normal (ULN) for age (for the purpose of this study, the ULN for SGPT is 45 U/L)

• Peripheral absolute neutrophil count (ANC) >= 1,000/mm^3 AND

• Platelet count >= 100,000/mm^3

• Patients enrolling on the standard risk arms must be medically fit to receive protocol treatment and with no contraindications to protocol treatment

• Eligibility criteria to participate in the pilot study of the AYA-Hears instrument (patient reported outcomes [PROs] of ototoxicity) Note: participants in group 1 will not receive AGCT1531 protocol-directed therapy; all other AYA-HEARS patients must be enrolled on the AGCT1531 SR2 arm in order to participate

• >= 11 and < 25 years old at enrollment

• Able to fluently speak and read English

• Has received prior cisplatin- or carboplatin-based chemotherapy regimen for malignancy including diagnoses other than germ cell tumor

• Followed for cancer or survivorship care at one of the following institutions:

• Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center

• Dana Farber/Harvard Cancer Center

• Hospital for Sick Children

• Children's Hospital of Eastern Ontario

• Oregon Health and Science University

• Seattle Children's Hospital

• Yale University

Exclusion Criteria:

• Patients with any diagnoses not listed including:

• Stage I testicular cancer patients who have undergone primary RPLND (retroperitoneal lymph node dissection)

• Pure dysgerminoma

• Pure mature teratoma

• Pure immature teratoma COG stage I, grade I

• Pure immature teratoma COG stage I, grade 2,3 with alpha-fetoprotein (AFP) >= 1000 ng/mL

• Pure immature teratoma COG stage II

•IV or FIGO stage IC to IV

• "Poor risk" GCT (age >= 11 years old and COG stage IV ovarian, COG stage III or IV EG, or IGCCC intermediate or poor risk testicular), or

• Primary central nervous system (CNS) germ cell tumor

• Germ cell tumor with somatic malignant transformation

• Spermatocytic seminoma

• Patients must have had no prior systemic therapy for the current cancer diagnosis

• Patients must have had no prior radiation therapy with the exception of CNS irradiation of brain metastases; (this exception only applies to SR1 patients; any patients over age 11 with distant metastases to brain [stage IV disease] would be considered poor risk and therefore not eligible for this trial)

• Patients with significant, pre-existing co-morbid respiratory disease that contraindicate the use of bleomycin are ineligible for the standard risk arms of the trial

• 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; (this criteria applies ONLY to patients who will receive chemotherapy [SR1 and SR2 patients])

• Lactating females who plan to breastfeed their infants; (this criteria applies ONLY to patients who will receive chemotherapy [SR1 and SR2 patients])

• Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation; (this criteria applies ONLY to patients who will receive chemotherapy [SR1 and SR2 patients])

Conditions & Interventions

Interventions:
Other: Best Practice, Biological: Bleomycin Sulfate, Drug: Carboplatin, Drug: Cisplatin, Drug: Etoposide, Other: Laboratory Biomarker Analysis, Other: Pharmacogenomic Study, Other: Quality-of-Life Assessment, Other: Questionnaire Administration

Conditions:
Childhood Extracranial Germ Cell Tumor, Extragonadal Embryonal Carcinoma, Germ Cell Tumor, Malignant Germ Cell Tumor, Malignant Ovarian Teratoma, Stage I Ovarian Choriocarcinoma, Stage I Ovarian Embryonal Carcinoma AJCC v6 and v7, Stage I Ovarian Teratoma AJCC v6 and v7, Stage I Ovarian Yolk Sac Tumor AJCC v6 and v7, Stage I Testicular Choriocarcinoma AJCC v6 and v7, Stage I Testicular Embryonal Carcinoma AJCC v6 and v7, Stage I Testicular Seminoma AJCC v6 and v7, Stage I Testicular Yolk Sac Tumor AJCC v6 and v7, Stage II Ovarian Choriocarcinoma, Stage II Ovarian Embryonal Carcinoma AJCC v6 and v7, Stage II Ovarian Yolk Sac Tumor AJCC v6 and v7, Stage II Testicular Choriocarcinoma AJCC v6 and v7, Stage II Testicular Embryonal Carcinoma AJCC v6 and v7, Stage II Testicular Yolk Sac Tumor AJCC v6 and v7, Stage III Ovarian Choriocarcinoma, Stage III Ovarian Embryonal Carcinoma AJCC v6 and v7, Stage III Ovarian Yolk Sac Tumor AJCC v6 and v7, Stage III Testicular Choriocarcinoma AJCC v6 and v7, Stage III Testicular Embryonal Carcinoma AJCC v6 and v7, Stage III Testicular Yolk Sac Tumor AJCC v6 and v7, Stage IV Ovarian Choriocarcinoma, Stage IV Ovarian Embryonal Carcinoma AJCC v6 and v7, Stage IV Ovarian Yolk Sac Tumor AJCC v6 and v7, Testicular Mixed Choriocarcinoma and Embryonal Carcinoma, Testicular Mixed Choriocarcinoma and Teratoma, Testicular Mixed Choriocarcinoma and Yolk Sac Tumor

More Information

Description: This partially randomized phase III trial studies how well active surveillance, bleomycin, carboplatin, etoposide, or cisplatin work in treating pediatric and adult patients with germ cell tumors. Active surveillance may help doctors to monitor subjects with low risk germ cell tumors after their tumor is removed. Drugs used in chemotherapy, such as bleomycin, carboplatin, etoposide, and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading.
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Phase: Phase 3
IRB Number: STUDY00003824
System ID: NCT03067181

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