



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: Male or Female
Age Group: Not specified

This study is NOT accepting healthy

volunteers

Inclusion Criteria:

- newly diagnosed with a Stage I germ cell tumor or metastatic germ cell tumor - see link to clinicaltrials.gov for detailed inclusion criteria

Exclusion Criteria:

- patients must have had no prior systemic therapy for the current cancer diagnosis - patients must have had no prior radiation therapy (exception of CNS irradiation of brain metastases for standard risk 1 patients) - female patients who are pregnant since fetal toxicities and teratogenic effects have been noted for several of the study drugs - lactating females who plan to breastfeed their infants - there are additional exclusion criteria (study staff will review)

Conditions & Interventions

Interventions:

Other: Best Practice, Procedure: Biopsy, Procedure: Biospecimen Collection, Biological: Bleomycin Sulfate, Drug: Carboplatin, Drug: Cisplatin, Procedure: Computed Tomography, Drug: Etoposide, Procedure: Magnetic Resonance Imaging, Other: Pharmacogenomic Study, Procedure: Pulmonary Function Test, Other: Quality-of-Life Assessment, Other: Questionnaire Administration

Conditions:

Cancer

Keywords:

Germ Cell Tumor, Malignant Germ Cell 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: PHASE3

IRB Number: SITE00000295

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