COG AGCT1532 - A Randomized Phase 3 Trial of Accelerated versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-risk Metastatic Germ Cell Tumors

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- between 11 years and 45 years old - confirmed germ cell tumour (non-seminoma or seminoma) OR Exceptionally raised tumour markers (AFP equal or greater than 1000ng/mL and/or HCG equal or greater than 5000 IU/L) - primary arising in testis, ovary, retro-peritoneum, or mediastinum - metastatic disease or non-testicular primary - see link to clinicaltrials.gov for completed Inclusion/Exclusion criteria

Exclusion Criteria:

- other primary malignancy (EXCEPT adequately treated non-melanomatous carcinoma of the skin, germ cell tumour, or other malignancy treated at least 5 years previously with no evidence of recurrence) - significant cardiac disease resulting in inability to tolerate IV fluid hydration for cisplatin - peripheral neuropathy equal or greater than grade 2 or clinically significant sensorineural hearing loss or tinnitus

Conditions & Interventions

Interventions:
Drug: Bleomycin (active name: Bleomycin Sulfate), Drug: Cisplatin, Drug: Etoposide, Drug: Filgrastim, Drug: Pegylated G-CSF (Pegfilgrastim)
Conditions:
Cancer
Keywords:
Germ Cell Tumor

More Information

Description: This trial is an open label, randomized, stratified 2-arm Australian-led multicenter phase 3 clinical trial undertaken in two stages. Participants (age >= 11 years and <= 45 years) with intermediate and poor-risk metastatic germ cell tumors will be randomized into either a “standard BEP” group or “accelerated BEP” group. Participants will be assigned to the two treatment arms in a 1:1 ratio and evaluated weekly, and then for 5 years after completing the study to assess the long-term effects of the chemotherapy. Bleomycin, Etoposide, Cisplatin (BEP) administered 3-weekly x 4 remains standard 1st line chemotherapy for intermediate- and poor-risk metastatic germ cell tumours (GCTs). BEP is accelerated by cycling Cisplatin and etoposide 2-weekly instead of 3-weekly. The aim of this study is to determine if accelerated BEP is superior to standard BEP as first-line chemotherapy for intermediate and poor risk metastatic GCTs.
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