Accelerating regimens of standard 3-weekly chemotherapy to 2-weekly cycles has improved cure more toxic. High-dose chemotherapy and more complex regimens have failed to improve cure rates and are treatment for patients with metastatic germ cell tumours (GCT) with poor prognostic features. Chemotherapy for GCT is safe, feasible, and active: The 5-year PFS was 94% and 50%, and 5-year OS was 94% and 92%, for intermediate and poor prognosis patients, respectively.1

Bleomycin, Etoposide, Cisplatin (BEP) administered as 4 x 3-weekly cycles is standard first-line chemotherapy for GCT as first-line chemotherapy. Results from an Australian phase I/II trial1,2 and a UK trial3 confirmed that accelerating standard chemotherapy for GCT is safe, feasible, and active: The 5-year PFS was 94% and 50%, and 5-year OS was 94% and 92%, for intermediate and poor prognosis patients, respectively.4

To determine if accelerated BEP is superior to standard BEP as first-line chemotherapy for intermediate and poor-risk metastatic GCT. Design: Open label, randomised, stratified, 2-arm, multicentre, 2-stage, phase 3 trial. Target Population: Participants aged 11 to 45 years with intermediate or poor-risk metastatic GCT, arising in testis, ovary, mediastinum considering retroperitoneum, or mediastinum with intermediate or poor-risk metastatic GCT. Sample Size: 150 (stage I) and 500 (stage II) patients gives >80% power at 5% level of significance to detect a 20% improvement in response rate from 59% with standard BEP to 80% with accelerated BEP (stage I), and 7% absolute improvement in 2yr PFS from 81% with standard BEP to 88% with accelerated BEP (stage II), respectively.

Primary Progression free survival
Secondary
- Response following treatment completion
- Adverse events
- Health related quality of life
- Treatment preference
- Delivered dose intensity
- Overall survival

Tertiary or Correlative Associations between biomarkers and their correlation with clinical outcomes.

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