POGO
PEDIATRIC ONCOLOGY GROUP OF ONTARIO
FOR KIDS WITH CANCER
FOR NOW, FOR LIFE.

AGCT 1531

Satellite Educational Training Module

JANUARY 2023

Presented to: Satellite Clinic Healthcare Providers
Presented by: Dr. Paul Gibson

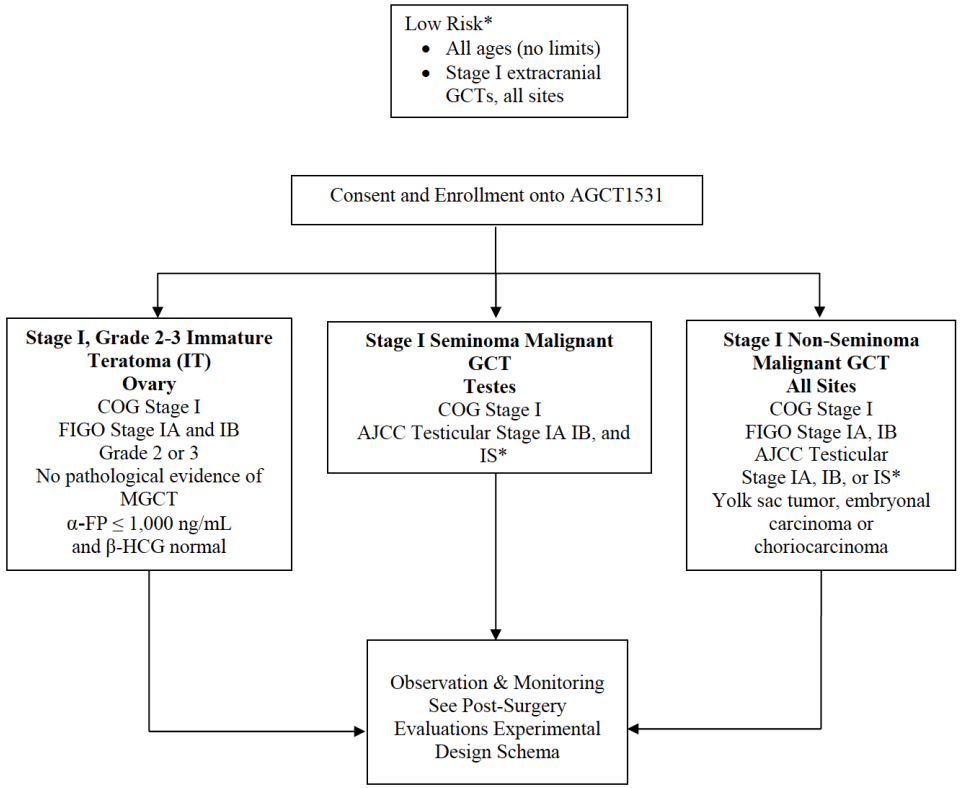
AGCT 1531

- 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

Background

- Although malignant germ cell tumors (MGCTs) account for only 3% of all tumors in children < 15 years of age, MGCT account for 15% of tumors between the ages of 15 - 29 and are the most common solid malignancy in AYA patients.
- 5 year overall survival exceeds 85%, however:
  - Significant long-term ototoxicity and nephrotoxicity
  - Life long increased risk of Second Malignant Neoplasm (SMN)
- AGCT 1531 explores 2 main strategies to decrease long term toxicity:
  - Build upon the goals of past COG germ cell tumor trials to eliminate chemotherapy in low-risk patients who are likely cured with surgery alone.
  - For patients who must undergo chemotherapy, test whether carboplatin can be substituted for cisplatin, thereby reducing toxicity.

Study Design: Low Risk



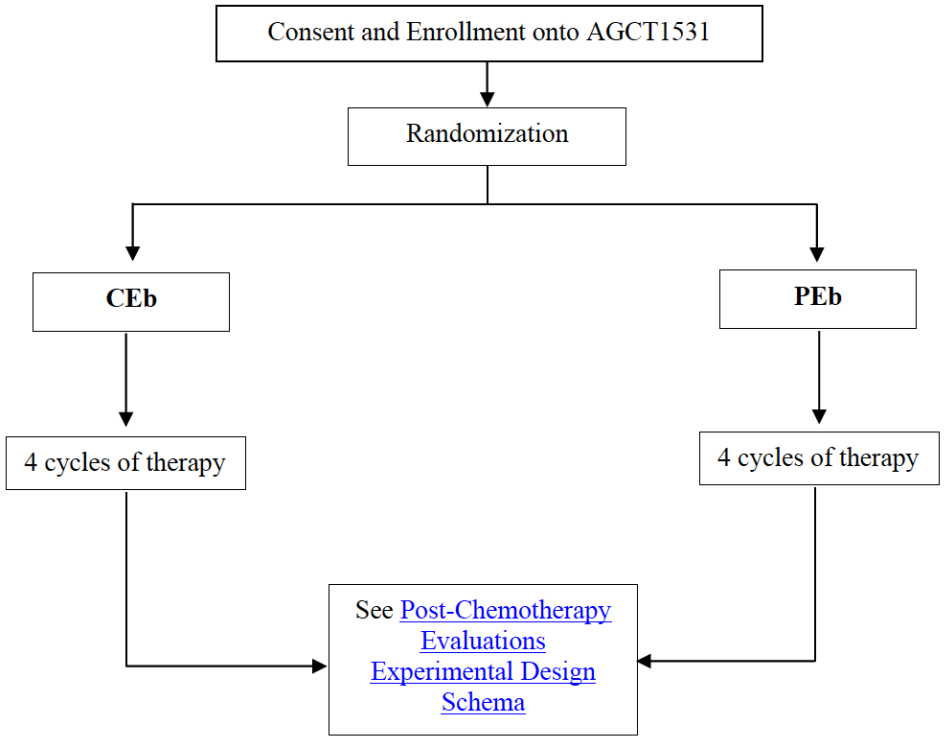
- Localized, Fully resected tumours will be followed by tumour markers (α-FP and β-HCG) and Imaging

Required Studies to be Obtained							
	Baseline	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Relapse**
Performance status	X						X
α-FP, β-HCG[1]	X	Every 2 months	Every 3 months	Annually	As clinically indicated	As clinically indicated	X
Recommended Baseline and Relapse Imaging to be Obtained							
Abdominal/Pelvic CT or MRI	X						X
Chest CT	X						X
CT or MRI of brain	Only if clinically indicated						Only if clinically indicated
Recommended Surveillance Imaging to be Obtained							
Abdominal/Pelvic CT or MRI		4 and 12 months	As clinically indicated				
Chest X-ray		4 and 12 months	As clinically indicated				
Optional specimens to be obtained (see Section 15.2 for complete details)							
Tumor Tissue	At diagnostic surgery						X
Serum	X[2]	4 and 12 months					X

Study Design: SR1 and SR2

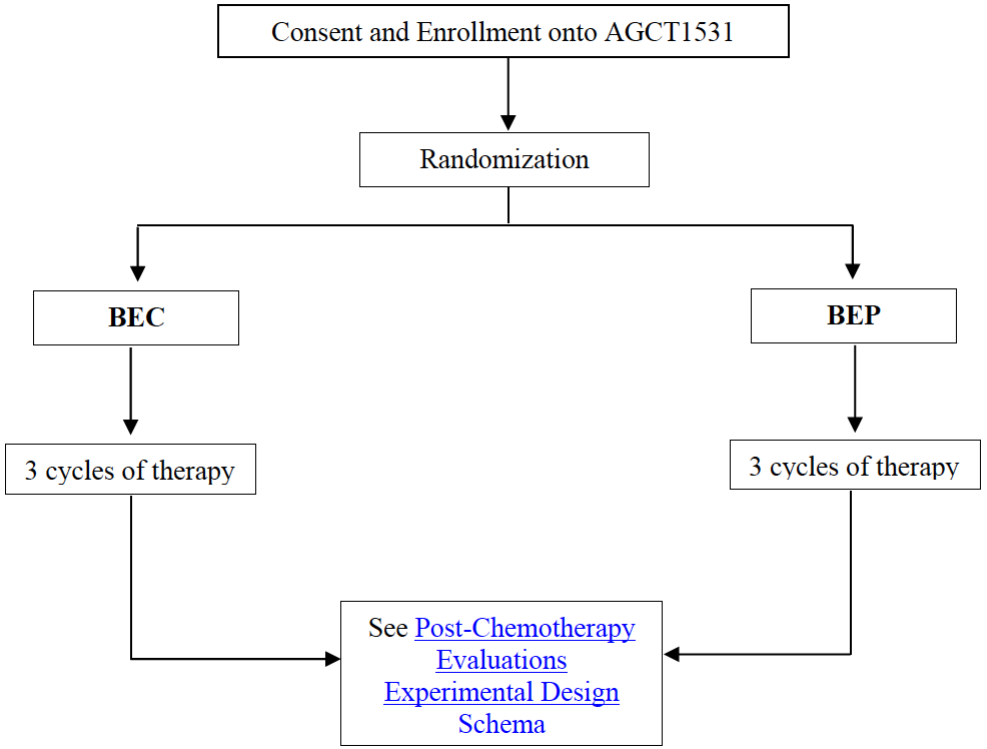
- Standard Risk 1 (SR1)
  - Age 0 < 11 years
  - Stage COG II IV extracranial GCTs, all sites
  - Malignant GCT (yolk sac tumor, embryonal carcinoma or choriocarcinoma)
- Standard Risk 2 (SR2)
  - Age ≥ 11 to < 25 years
  - Ovarian, COG Stage II III , FIGO IC-III
  - Extragonadal, COG Stage II
  - Testicular COG Stage II IV and IGCCC Good Risk
  - Malignant GCT (yolk sac tumor embryonal carcinoma or choriocarcinoma)
- TWO different SR groups FOUR Total arms of therapeutic study
  - When administering chemo in satellite, be sure to confirm SR AND ARM

Therapy: SR-1



- CEb
  - Carboplatin (Day 1)
  - Bleomycin (Day 1)
  - Etoposide (Days 1-5)
  - Generally OUTpatient therapy
- PEb
  - Cisplatin (Days 1-5)
  - Bleomycin (Day 1)
  - Etoposide (Days 1-5)
  - Generally INpatient therapy
- FOUR Cycles of therapy

Therapy: SR-2



- BEC
  - Carboplatin (Day 1)
  - Bleomycin (Day 1, **8, 15**)
  - Etoposide (Days 1-5)
  - Generally OUTpatient therapy
- BEP
  - Cisplatin (Days 1-5)
  - Bleomycin (Day 1, **8, 15**)
  - Etoposide (Days 1-5)
  - Generally INpatient therapy
- THREE Total Cycles

What do I need to know at the satellite?

- The Drug Reminders of important toxicities
  - **Cisplatin:** Highly Emetogenic, Risk of Delayed Nausea and Vomiting, Tubulopathy (Mg, PO4, K,)
  - **Carboplatin:** Infusional reactions (including anaphylaxis, more common with repeated (>6) cycles
  - **Bleomycin:** Acute Fever and Rash, Chronic Pulmonary Toxicity (PFTs to be monitored at referring sites)
  - **Etoposide:** Infusional Reactions (Transient hypotension, can be improved by slowing infusion) True anaphylaxis
- Refer to protocol document for full review of Common, Occasional and Rare toxicities

What do I need to know at the satellite?

- Low Risk
  - Satellites may be asked to share follow-up observations, particularly lab work (α-FP and β-HCG)
- Standard Risk
  - Satellites may administer outpatient chemotherapy (Particularly in Carboplatin Arms)
  - Satellites may be asked to see for follow-up blood work (CBCs, electrolytes) and provide transfusion and/or electrolyte support
  - All patients on chemotherapy will receive myeloid growth factor, confirm with referring centre if the agent is filgrastim (given daily) or pegfilgrastim (given once)

Training Complete

Click here for your Certificate of Completion for AGCT 1531.

1. Download your certificate.
2. Enter your name, POGO Satellite Clinic, and the date.
3. Save your Certificate of Completion for your records.
4. Email a copy to Usama Memon (umemon@pogo.ca).

Upon receiving your Certificate of Completion, POGO notifies your affiliated tertiary hospital(s) that your training for AGCT 1531 is complete.

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