# Essai Clinique

Généré le 16 mai 2025 à partir de

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| Titre | Étude de phase III, portant sur la surveillance active des patients atteints d'une tumeur des cellules germinales de faible risque, et essai clinique à répartition aléatoire, visant à administrer la carboplatine ou le cisplatine aux patients pédiatriques de risque standard, et patients adultes atteints d'une tumeur des cellules germinales |
| Protocole ID | COG-AGCT-1531 |
| ClinicalTrials.gov ID | NCT03067181 |
| Type(s) de cancer | Pédiatrique divers |
| Phase | Phase III |
| Médicament | bleomycin, carboplatin, etoposide, cisplatin |
| Institution | CHU DE QUEBEC – UNIVERSITE LAVAL<br>CHUL ET CENTRE MERE-ENFANT SOLEIL<br>2705 boulevard Laurier, Québec, QC, G1V 4G2 |
| Ville | Québec |
| Investigateur principal | Dr Bruno Michon |
| Coordonnateur | Barbara Desbiens<br>418-525-4444 poste 40195 |
| Statut | Actif en recrutement |
| But étude | 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. |
| Critères d'éligibilité | • Ages Eligible for Study: up to 49 Years (Child, Adult)<br>• Low risk stratum (stage I ovarian immature teratoma and stage I malignant GCT [all sites]): Patients must be < 50 years of age at enrollment<br>• Standard risk 1: Patient must be < 11 years of age at enrollment<br>• Standard risk 2: Patients must be >= 11 and < 25 years of age at enrollment<br>• Newly diagnosed patients must have histologic verification of a primary extracranial germ cell tumor in any of the categories outlined; elevation of serum tumor markers without histologic confirmation is not sufficient for entry on the trial<br>  • NOTE: for low risk patients, materials for rapid surgical central review must be sent within 7 days of study enrollment<br>• 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, mixed immature and mature teratoma, (no pathological evidence of mediastinal germ cell tumor [MGCT]); tumor markers: alpha-FP =< 1,000 ng/mL, beta-HCG institutional normal; age (years) < 50<br>• Low risk stage I MCGT; site: ovarian, testicular, or extragonadal; stage: COG stage I, FIGO stage IA and IB, American Joint Committee on Cancer (AJCC) testicular stage IA and IB; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma (pure or mixed); age (years) < 50<br>• Standard risk 1 (SR1); site: ovarian, testicular, or extragonadal; stage: COG stage II-IV, FIGO stage IC, FIGO stage II-IV; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma (pure or mixed); age (years) < 11<br>• Standard risk 2 (SR2)<br>  • 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 (pure or mixed); age (years) >= 11 and < 25 |

- Site: testicular; stage: COG stage II-IV, AJCC stage II, III, International Germ Cell Consensus Classification (IGCCC) good risk; histology: must contain at least one of the following: yolk sac tumor, embryonal carcinoma, or choriocarcinoma (pure or mixed); tumor markers: for IGCCC good risk: alpha-FP < 1,000 ng/mL, beta-HCG < 5,000 IU/mL and lactate dehydrogenase (LDH) < 1.5 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 (pure or mixed) age (years) >= 11 and < 25

- Patients must have a performance status corresponding to Eastern Cooperative Oncology Group (ECOG) scores of 0, 1 or 2; use Karnofsky for patients > 16 years of age and Lansky for patients =< 16 years of age
- Creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 mL/min/1.73 m^2
- 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)
- No evidence of dyspnea at rest, no exercise intolerance, and a pulse oximetry > 94% if there is clinical indication or determination; pulmonary function tests (PFTs) are not required
- Eligibility criteria to participate in group 1 of the pilot study of the AYA-Hears instrument Note: participants in group 1 will not receive protocol-directed therapy
- >= 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:
  - 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
- Has experienced prior or ongoing hearing impairment due to chemotherapy or radiotherapy as defined by one of the following:
  - Society of Pediatric Oncology (SIOP) grade 1 hearing loss
  - Subjective (patient-reported) hearing difficulties
  - Subjective (patient-reported) tinnitus

Critères d'exclusion

- Patients with any diagnoses not listed including:
  - Stage I testicular cancer patients who have undergone primary RPLND (retroperitoneal lymph node dissection)
  - Pure dysgerminoma and pure seminoma
  - Pure mature teratoma
  - Pure immature teratoma COG stage I with alpha-fetoprotein (AFP) >= 1000 ng/mL
  - Pure immature teratoma COG stage II - IV or FIGO stage IC to IV
  - Poor risk disease (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
- Patients must have had no prior systemic therapy
- 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)
- SR1 and SR2 patients:
- Female patients who are pregnant; a pregnancy test is required for female patients of childbearing potential
- Lactating females who plan to breastfeed their infants
- Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation