Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients With Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum
Protocole ID	NRG-GY019
ClinicalTrials.gov ID	NCT04095364
Type(s) de cancer	Ovaire
Phase	Phase III
Type étude	Clinique
Médicament	Paclitaxel+Carboplatine et létrozole en entretien versus létrozole entretien seul
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Diane Provencher
Coordonnateur	France Gauthier 514-890-8000 poste 30921
Statut	Actif en recrutement
Date d'activation	18-01-2024
But étude	This phase III trial studies how well letrozole with or without paclitaxel and carboplatin works in treating patients with stage II-IV low-grade serous carcinoma of the ovary, fallopian tube, or peritoneum. Letrozole is an enzyme inhibitor that lowers the amount of estrogen made by the body which in turn may stop the growth of tumor cells that need estrogen to grow. Drugs used in chemotherapy, such as paclitaxel and carboplatin, 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. It is not yet known whether giving letrozole alone or in combination with paclitaxel and carboplatin works better in treating patients with low-grade serous carcinoma of the ovary, fallopian tube, or peritoneum compared to paclitaxel and carboplatin without letrozole.

Critères d'éligibilité	• Patients must have newly diagnosed, stage II-IV low-grade serous ovarian cancer (submission of pathology report[s] required). Ovarian cancer = ovarian, fallopian tube and primary peritoneal cancers
	  • NOTE: Patients with a prior history of serous borderline tumors but a new diagnosis of stage II-IV low-grade serous ovarian cancer are eligible
	  • p53 immunohistochemistry (IHC) is required and must show nonaberrant pattern (nonaberrant p53 expression is consistent with normal/wildtype TP53)
	  • A copy of the pathology report that includes the diagnosis of low grade serous ovarian cancer and nonaberrant p53 IHC result must be submitted in RAVE. NOTE: If aberrant p53 expression is found on p53 IHC, the patient is NOT eligible (aberrant p53 expression is consistent with mutant TP53 and supports diagnosis of high grade serous ovarian cancer)
	• Appropriate stage for study entry based on the following diagnostic workup:
	  • History/physical examination within 14 days prior to registration;
	  • Radiographic tumor assessment within 28 days prior to registration. (23-MAY-2023)
	• Age >= 18
	• Patients must have undergone an attempt at maximal upfront cytoreductive surgery, with either optimal (=< 1 cm diameter residual disease/nodule) or suboptimal residual disease (> 1 cm diameter residual disease/nodule) status allowed
	• Patients must have undergone a bilateral salpingo-oophorectomy

	• Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2 within 14 days prior to registration • Patients must be within =< 8 weeks of primary cytoreductive surgery at time of randomization • Patients must be able to take per oral (P.O.) medications • Absolute neutrophil count (ANC) greater than or equal to 1,500/mcl (within 14 days prior to registration) • Platelets greater than or equal to 100,000 cells/mcl (within 14 days prior to registration) • Creatinine less than or equal to 1.5 x upper limit of normal (ULN) (within 14 days prior to registration) • Bilirubin less than or equal to 1.5 x ULN (within 14 days prior to registration) • Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) less than or equal to 3 x ULN (within 14 days prior to registration) • The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the United States (U.S.), authorization permitting release of personal health information • Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial

Critères d'exclusion	• Patients may not have received neoadjuvant or adjuvant chemotherapy or radiotherapy for the treatment of this disease
	• Patients may not have received previous hormonal therapy for the treatment of this disease
	• Patients with known hypersensitivity to letrozole or hypersensitivity/intolerance to carboplatin/paclitaxel therapy
	• Patients with severe cardiac disease:
	  • Myocardial infarction or unstable angina within 6 months prior to registration
	  • New York Heart Association (NYHA) class II or greater congestive heart failure
	• Patients with known central nervous system metastases
	• Patients with active (except for uncomplicated urinary tract infection) or uncontrolled systemic infection
	• Patients with >= grade 2 baseline neuropathy
	• Known human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial