Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Étude multicentrique, randomisée, contrôlée par placebo, à double insu, de phase III du durvalumab en association avec une chimiothérapie et du bevacizumab, suivis d'un traitement d'entretien avec durvalumab, bevacizumab et olaparib, chez des patientes atteintes d'un cancer de l'ovaire avancé récemment diagnostiqué (DUO-O)
Protocole ID	DUO-O
ClinicalTrials.gov ID	NCT03737643
Type(s) de cancer	Ovaire
Phase	Phase III
Stade	Première intention de traitement
Type étude	Traitement
Médicament	Durvalumab avec chimiothérapie et Bevacizumab, suivi de Maintient avec Durvalumab, Bevacizumab et Olaparib
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Vincent Castonguay
Coordonnateur	Maryse Gingras 418-691-5781
Statut	Fermé
But étude	Eligible patients will be those patients with newly diagnosed, histologically confirmed advanced (Fédération Internationale de Gynécologie et d'Obstétrique [FIGO] Stage III-IV) ovarian, primary peritoneal cancer and/or fallopian-tube cancer. All patients should be candidates for cytoreductive surgery which could be conducted as immediate upfront primary surgery following diagnosis or can be conducted after initiation of platinum based neoadjuvant chemotherapy. All patients should be eligible to start first line platinum based chemotherapy in combination with bevacizumab. The study aims to evaluate the efficacy and safety of standard of care (SoC) platinum-based chemotherapy and bevacizumab followed by maintenance bevacizumab either as monotherapy, or in combination with durvalumab, or in combination with durvalumab and olaparib. Therefore, this study aims to see which combination allows patients to live longer without the cancer coming back or getting worse. The study is also looking to see which combination makes patients live longer and how the treatment and the cancer affects their quality of life.
Critères d'éligibilité	Female patients with newly diagnosed, histologically confirmed, advanced (Stage III-IV) high grade epithelial ovarian cancer including high grade serious, high grade endometriod, clear cell ovarian cancer or carcinosarcoma, primary peritoneal cancer and / or fallopian-tube cancer • Patients must be aged ≥18 years of age. For patients enrolled in Japan that are aged <20 year • All patients should be candidates for cytoreductive surgery either: upfront primary surgery OR plan to undergo chemotherapy with interval debulking surgery • Evidence of presence or absence of BRCA1/2 mutation in tumour tissue • Mandatory provision of tumour sample for centralised tBRCA testing • ECOG performance status 0-1 • Patients must have preserved organ and bone marrow function • Postmenopausal or evidence of non-childbearing status for women of childbearing potential: negative urine or serum pregnancy test

Critères d'exclusion	Non-epithelial ovarian cancer, borderline tumors, low grade epithelial tumors or mucinous histology • Prior systemic anti-cancer therapy for ovarian cancer • Inability to determine the presence or absence of a deleterious or suspected deleterious BRCA mutation • Prior treatment with PARP inhibitor or immune mediated therapy • Planned intraperitoneal cytotoxic chemotherapy • Active or prior documented autoimmune or inflammatory disorders • Patients considered a poor medical risk due to a serious, uncontrolled intercurrent illness • Clinically significant cardiovascular disease • Patients with known brain metastases • History of another primary malignancy except for: • Malignancy treated with curative intent and with no known active disease ≥5 years before the first dose of study treatment and of low potential risk for recurrence (patients who have received prior adjuvant chemotherapy for early stage breast cancer may be eligible, provided that it was completed ≥3 years prior to registration, and that the patient remains free of recurrent or metastatic disease) • Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease • Adequately treated carcinoma in situ without evidence of disease • Endometrial cancer FIGO Stage IA, Grade 1 or Grade 2 • Persistent toxicities CTCAE Grade >2 caused by previous cancer therapy • Patients with a known hypersensitivity to olaparib, durvalumab or any of the excipients of these products and to the combination/comparator agents • Breast feeding women