Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	A Randomised, Multicentre, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination With Durvalumab, Followed by Maintenance Durvalumab With or Without Olaparib in Patients With Newly Diagnosed Advanced or Recurrent Endometrial Cancer
Protocole ID	DUO-E
ClinicalTrials.gov ID	NCT04269200
Type(s) de cancer	Endomètre
Phase	Phase III
Type étude	Clinique
Médicament	Carboplatine et paclitaxel en association avec le durvalumab, suivi d'un traitement d'entretien avec durvalumab avec ou sans olaparib
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
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Statut	Fermé
But étude	A study to assess the efficacy and safety of durvalumab in combination with platinum-based chemotherapy (paclitaxel + carboplatin) followed by maintenance durvalumab with or without olaparib for patients with newly diagnosed advanced or recurrent endometrial cancer.
Critères d'éligibilité	• Age ≥18 years at the time of screening and female. • Histologically confirmed diagnosis of epithelial endometrial carcinoma. All histologies, including carcinosarcomas, will be allowed. Sarcomas will not be allowed. • Patient must have endometrial cancer in one of the following categories: 1. Newly diagnosed Stage III disease (measurable disease per RECIST 1.1 following surgery or diagnostic biopsy), 2. Newly diagnosed Stage IV disease (with or without disease following surgery or diagnostic biopsy) 3. Recurrence of disease where the potential for cure by surgery alone or in combination is poor. • Naïve to first line systemic anti-cancer treatment. For patients with recurrent disease only, prior chemotherapy is allowed only if it was administered in the adjuvant setting and there is at least 12 months from date of last dose of chemotherapy administered to date of subsequent relapse • FPPE tumor sample must be available for MMR evaluation. • Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days of starting study treatment.
Critères d'exclusion	• History of leptomeningeal carcinomatosis. • Brain metastases or spinal cord compression. • Prior treatment with PARP inhibitors. • Prior immune checkpoint inhibitors or prior treatment with an agent directed to a stimulatory or co-inhibitor T-cell receptor other than anti-PD-1, anti-PD-L1, or anti-PD-L2 agent.