Essai Clinique

Généré le 18 avr. 2024 à partir de

Titre	A Phase 3 Multicenter, Randomized Study of Rucaparib Versus Chemotherapy in Patients With Relapsed, BRCA Mutant, High Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
Protocole ID	ARIEL4
ClinicalTrials.gov ID	NCT02855944
Type(s) de cancer	Ovaire
Phase	Phase III
Stade	Maladie réfractaire
Type étude	Traitement
Médicament	Rucaparib
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
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Statut	Fermé
But étude	The purpose of this study is to determine how patients with ovarian, fallopian tube, and primary peritoneal cancer will best respond to treatment with rucaparib versus chemotherapy.
Critères d'éligibilité	• Be 18 years of age at the time the informed consent form is signed • Have a histologically confirmed Grade 2 or Grade 3 endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer • Received ≥ 2 prior chemotherapy regimens and have relapsed or progressive disease as confirmed by radiologic assessment • Have biopsiable and evaluable disease. Note: biopsy is optional for patients known to harbor a BRCA1/2 mutation • Have sufficient archival formalin-fixed paraffin-embedded (FFPE) tumor tissue available for planned analyses
Critères d'exclusion	• History of prior cancers except for those that have been curatively treated, with no evidence of cancer currently (provided all chemotherapy was completed >6 months prior and/or bone marrow transplant >2 years prior to first dose of rucaparib). • Prior treatment with any PARP inhibitor • Symptomatic and/or untreated central nervous system metastases • Pre-existing duodenal stent and/or any other gastrointestinal disorder or defect that would, in the opinion of the Investigator, interfere with absorption of rucaparib • Women who are pregnant or breast feeding • Hospitalization for bowel obstruction within 3 months prior to enrollment