Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Étude multicentrique à répartition aléatoire de phase III visant à comparer le rucaparib à la chimiothérapie chez des patientes atteintes d'un cancer épithélial de l'ovaire récidivant de haut grade avec mutation BRCA, d'un cancer des trompes de Fallope ou d'un cancer péritonéal primitif
Protocole ID	CO-338-043 (ARIEL4)
ClinicalTrials.gov ID	NCT02855944
Type(s) de cancer	Ovaire
Phase	Phase III
Stade	Maladie réfractaire
Type étude	Traitement
Médicament	Rucaparib
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Diane Provencher
Coordonnateur	Shirley Truchon 514-890-8000 poste 25350
Statut	Fermé
Date d'activation	08-03-2017
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