Essai Clinique

Généré le 17 avr. 2024 à partir de

Titre	A Phase II, Open-Label, Randomized, Multi-Centre Study, of Neoadjuvant Olaparib in Patients With Platinum Sensitive Recurrent High Grade Serous Ovarian/Primary Peritoneal or Fallopian Tube Cancer
Protocole ID	OZM-058 (NEO)
ClinicalTrials.gov ID	NCT02489006
Type(s) de cancer	Ovaire
Phase	Phase II
Stade	Récidive
Type étude	Traitement
Médicament	Olaparib
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	This is a study that will look at the effects and how useful investigational drug olaparib is as a neoadjuvant treatment (treatment given as to shrink a tumor before the main treatment) prior to surgery in patients with recurrent ovarian, primary peritoneal or fallopian tube cancer.
Critères d'éligibilité	• Histologically proven recurrent high grade serous ovarian/primary peritoneal or fallopian tube cancer. • Patients must have disease amenable to pre-operative biopsy. • Patients must have disease deemed suitable for surgical debulking. • Patients must have a progression free interval of at least 6 months prior to registration. • Patients must have had at least one line of platinum based therapy. • Patients must have shown platinum sensitivity to their last line of platinum therapy • Age >=18 years • ECOG performance status 0-1 within 7 days of registration • Life expectancy of greater than 3 months • Patients must have normal organ and marrow function • Women of child-bearing potential must agree to use adequate contraception prior to study entry and for the duration of study participation. • Ability to understand and the willingness to sign a written informed consent document. • Subject's willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures.
Critères d'exclusion	• History of allergic reactions attributed to compounds of similar chemical or biologic composition to olaparib. • History of allergic reactions attributed to platinum precluding further use. • Radiation therapy within 4 weeks of registration • Use of any other systemic, targeted, immunotherapy, chemotherapy, or investigational agents within 4 weeks of registration • Previously received a PARP inhibitor

- Other malignancy within the last 2 years with exceptions
- Patients considered a poor medical risk due to a serious, uncontrolled medical disorder, non-malignant systemic disease or active, uncontrolled infection.
- Patients unable to swallow orally administered medication and patients with gastrointestinal disorders likely to interfere with absorption of the study medication.
- Concomitant use of known potent CYP3A4 inhibitors
- Concomitant use of known potent CYP3A4 inducers
- Other anti-cancer therapy including immunotherapy, hormonal therapy, biological therapy, other novel agents or investigational agents
- Persistent toxicities (CTCAE v 4.03 grade >2) caused by previous cancer therapy, excluding alopecia
- Patients with myelodysplastic syndrome/acute myeloid leukemia
- Patients with brain metastases
- Immunocompromised patients, e.g., patients who are known to be serologically positive for human immunodeficiency virus (HIV)
- Patients with known active hepatitis (i.e., hepatitis B or C) due to risk of transmitting the infection through blood or other body fluids
- Pregnant or breastfeeding women
- Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or study drug administration, or may interfere with the interpretation of study results, and in the judgment of the investigator would make the subject inappropriate for entry into this study.