Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Étude de phase III randomisée et à double insu comparant un traitement à base de platine avec TSR-042 et niraparib par rapport au traitement standard à base de platine seul comme traitement de première intention du cancer de l'ovaire épithélial non muqueux de stade III ou IV
Protocole ID	FIRST
ClinicalTrials.gov ID	NCT03602859
Type(s) de cancer	Ovaire
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Chimiothérapie à base de platine + TSR-042 puis Niraparib et TSR-042 en maintien
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
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Statut	Fermé
But étude	This is a global, multicenter, randomized, double-blind, controlled Phase 3 study in patients with newly diagnosed, Stage III or IV non mucinous epithelial ovarian, fallopian tube, or peritoneal cancer (collectively referred to as "ovarian cancer"). The currently recommended standard of care therapy for the first line treatment of Stage III or IV ovarian cancer is the combination of paclitaxel and carboplatin, with or without concurrent and maintenance bevacizumab.
Critères d'éligibilité	• Patients with a histologically confirmed diagnosis of high-grade nonmucinous epithelial ovarian cancer (serous, endometrial, clear cell, carcinosarcoma, an mixed pathologies) that is Stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) or tumor, node and metastasis staging criteria. • All patients with Stage IV disease are eligible. This includes those with inoperable disease, those who undergo primary debulking surgery (complete cytoreduction (CC0) or macroscopic disease), or those for whom neoadjuvant chemotherapy is planned. • Patients with Stage III are eligible if they meet one or more of the following criteria: • High risk Stage IIIC disease. • Planning to receive neoadjuvant chemotherapy. • Patients must provide a blood sample for research at Screening. • Patient must provide a formalin-fixed paraffin embedded tumor tissue sample at Screening for research. • Patients must have adequate organ function (Note: complete blood count test should be obtained without transfusion or receipt of stimulating factors within 2 weeks before obtaining Screening blood sample) • Patients must have an ECOG score of 0 or 1. • Patients must have normal BP or adequately treated and controlled hypertension (systolic BP ≤140 mmHg and/or diastolic BP ≤90 mmHg). • Patients must agree to complete HRQoL questionnaires throughout the study. • Patients must be able to take oral medication.

Critères d'exclusion	• Patient has mucinous, germ cell, transitional cell, or undifferentiated tumor. • Patient has low-grade or Grade 1 epithelial ovarian cancer. • Stage III patient with complete cytoreduction (CC0) resection after primary debulking surgery (ie, no macroscopic residual disease, unless the patient has aggregate 5 cm extra-pelvic disease during primary debulking surgery. • Patient has not adequately recovered from prior major surgery. • Patient has a known condition, therapy, or laboratory abnormality that might confound the study results or interfere with the patient's participation for the full duration of the study treatment in the opinion of the Investigator. • Patient has been diagnosed and/or treated with any therapy for invasive cancer <5 years from study enrollment, completed adjuvant chemotherapy and/or targeted therapy (eg, trastuzumab) less than 3 years from enrollment, or completed adjuvant hormonal therapy less than 4 weeks from enrollment. Patients with definitively treated non-invasive malignancies such as cervical carcinoma in situ, ductal carcinoma in situ, Grade 1 or 2, Stage IA endometrial cancer, or non-melanomatous skin cancer are allowed. • Patient is at increased bleeding risk due to concurrent conditions (eg, major injuries or major surgery within the past 28 days prior to start of study treatment and/or history of hemorrhagic stroke, transient ischemic attack, subarachnoid hemorrhage, or clinically significant hemorrhage within the past 3 months). • Patient is immunocompromised. Patients with splenectomy are allowed. Patients with well-controlled known human immunodeficiency virus (HIV) are allowed. • Patient has known active hepatitis B (eg, hepatitis B surface antigen reactive) or hepatitis C (eg, hepatitis C virus ribonucleic acid [qualitative] is detected). • Patient is considered a poor medical risk due to a serious, uncontrolled medical disorder, non-malignant systemic disease, or active, uncontrolled infection. • Patient has had investigational therapy administered within 4 weeks or within a time interval less than at least 5 half-lives of the investigational agent, whichever is longer, prior to the first scheduled day of dosing in this study. • Patient has received a live vaccine within 14 days of planned start of study therapy. Seasonal influenza vaccines that do not contain live viruses are allowed. • Patient has a known contraindication or uncontrolled hypersensitivity to the components of paclitaxel, carboplatin, niraparib, bevacizumab, TSR-042, or their excipients.