Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	FIGO 2018 Stage IB2 (?2 to
Protocole ID	CoNteSSa (NeoCon-F)
ClinicalTrials.gov ID	NCT04016389
Type(s) de cancer	Col
Phase	Autres
Type étude	Clinique
Médicament	Chimiothérapie néo-adjuvante
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Vanessa Samouëlian
Coordonnateur	France Gauthier 514-890-8000 poste 30921
Statut	Actif en recrutement
But étude	This study will include patients with invasive cervical cancer that wish to keep their fertility as much as possible in the future after treatment. Patients who receive surgery alone may experience long-term side effects including infertility. The purpose of this research study is to determine whether giving neo-adjuvant chemotherapy prior to surgery can maintain fertility in patients with invasive cervical cancer. The neo-adjuvant chemotherapy will consist of a platinum-based chemotherapy drug cisplatin or carboplatin, with a chemotherapy drug called paclitaxel. These are common chemotherapy drugs used in the treatment of women with cervical cancers.
Critères d'éligibilité	Part 1 - Eligibility Criteria for Neoadjuvant Chemotherapy • Patients must have histologically confirmed invasive cervical cancer with adenocarcinoma, adenosquamous or squamous histology and FIGO 2018 IB2 measuring ≥2cm to <4cm by radiological imaging (MRI). • Patients must be premenopausal and wish to preserve fertility. • At time of registration, patient may not have had any prior therapy to treat their cancer lesion. • Eastern Cooperative Group (ECOG) performance status ≤ 2. • Within 7 days of the proposed start of treatment, patients must have normal organ and marrow function. • No evidence of active uncontrolled infection (patients on antibiotics are eligible). • Patient must have disease that is measurable per the Response Evaluation Criteria in Solid Tumors (RECIST) 1.1. • Ability to understand and willing to sign a written informed consent document. • Patients must agree to use effective contraceptive methods prior to study entry, during study participation, and for at least one year after the fertility-sparing surgery (FSS) procedure. A serum pregnancy test within 72 hours prior to study registration is required. Part 2 - Eligibility Criteria for Fertility Sparing Surgery (FSS) • Completed 3 cycles of neo-adjuvant chemotherapy and achieved a complete response (CR) or partial response (PR) with reduction of the lesion to <2 cm on physical examination and MRI.

Critères d'exclusion	Part 1 - Exclusion Criteria for Neoadjuvant Chemotherapy • Patients who have had chemotherapy or radiotherapy or surgery for their cancer. • Patients who are receiving any other investigational agents. • Patients with other cancers requiring ongoing treatment. • Patients with known / evidence of brain metastases are excluded from participation in this clinical trial. • History of allergic reactions attributed to compounds of similar chemical or biologic composition to paclitaxel, carboplatin, or cisplatin or other agents used in study. • Uncontrolled inter-current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements. • Patients who are pregnant or breastfeeding • Any other condition that would, in the Investigator's judgment, contraindicate the patient's participation in the clinical study due to safety concerns or compliance with clinical study procedures, e.g., infection/inflammation, intestinal obstruction, unable to swallow medication, social/ psychological issues. Part 2 - Exclusion Criteria for Fertility Sparing Surgery • Patient unable to complete 3 cycles of neoadjuvant chemotherapy • Suboptimal response to neoadjuvant chemotherapy according to investigator • Residual lesion > 2cm or disease progression while on chemotherapy