Essai Clinique

Généré le 29 avr. 2025 à partir de

Titre	Image Guided Intensity Modulated External Beam Radiochemotherapy and MRI Based Adaptive BRAchytherapy in Locally Advanced CErvical Cancer
Protocole ID	EMBRACE 2
ClinicalTrials.gov ID	NCT03617133
Type(s) de cancer	Col
Phase	Phase II
Stade	Localement avancé
Type étude	Traitement
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Israël Fortin
Coordonnateur	Véronique Tran 514-252-3400 poste 3227
Statut	Actif en recrutement
But étude	The research group on adaptive image-guided radiotherapy for locally advanced cervical carcinoma completed the protocol for the EMBRACE II study in October 2018. This study will be carried out in the next few years at the University Clinic for Radiotherapy at the Medical University of Vienna and other international partner institutes. EMBRACE II builds on the findings of the current EMBRACE study. These are already implemented in everyday clinical practice in order to further improve the accuracy of the entire therapy of cervical carcinomas, using state-of-the-art techniques of tele- and brachytherapy. The aim of the EMBRACE II study is to maintain and enhance the excellent local tumor control as well as the nodal and systemic control for all tumor stages while minimizing the adverse reaction rates for all affected organs (rectum, sigmoid, urinary bladder, and vagina) to increase the quality of life of patients with cervical carcinomas.
Critères d'éligibilité	• Cancer of the uterine cervix considered suitable for curative treatment with definitive radio-(chemo)therapy including MRI guided BT • Positive biopsy showing squamous-cell carcinoma, adenocarcinoma or adeno-squamous cell carcinoma of the uterine cervix. • Staging according to FIGO and TNM guidelines • MRI of pelvis at diagnosis is performed • MRI, CT or PET-CT of the retroperitoneal space and abdomen at diagnosis is performed • MRI with the applicator in place at the time of (first) BT will be performed • Para-aortic metastatic nodes below L1-L2 are allowed • Patient informed consent
Critères d'exclusion	• Other primary malignancies except carcinoma in situ of the cervix and basal cell carcinoma of the skin • Small cell neuroendocrine cancer, melanoma and other rare cancers in the cervix • Metastatic disease above and beyond the retroperitoneal para-aortic L1-L2 interspace • Previous pelvic or abdominal radiotherapy • Previous total or partial hysterectomy • Combination of preoperative radiotherapy with surgery • Patients receiving BT only • Patients receiving EBRT only

- Patients receiving neo-adjuvant chemotherapy or other forms of antineoplastic treatment apart from weekly concomitant cisplatin (40 mg/2). However, adjuvant chemotherapy in the form of 4 courses of 3 weekly Carboplatin (AUC 5) and Paclitaxel (155 mg/m2) is allowed according to departmental policy.
- Contra indications to MRI
- Contra indications to BT