Essai Clinique

Généré le 23 avr. 2024 à partir de

Titre	Meilleure préservation d'organe : Proposition d'étude multicentrique (Morpheus) comparant la curiethérapie à haut débit de dose à la radiothérapie externe guidée par l'image – Une étude de phase III à répartition aléatoire
Protocole ID	Morpheus study (no surgery)
ClinicalTrials.gov ID	NCT03051464
Type(s) de cancer	Côlon et rectum
Type étude	Clinique
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
Investigateur principal	Dre Té Vuong
Coordonnateur	Emma Starr 514-340-8222 poste 28443
Statut	Actif en recrutement
But étude	A pilot study of 40 patients. Patients with a clinical T2-3 N0-1 rectal cancer will be randomized to two arms (arm A: standard chemoradiation (45 Gy in 25 with concomitant 5-FU or Xeloda chemotherapy) and an external beam boost of 9 Gy compared to arm B: standard chemoradiation (45 Gy in 25 with concomitant 5-FU or Xeloda chemotherapy) and followed by a brachytherapy boost of 30 Gy in 3 fractions).
Critères d'éligibilité	• Rectal cancer patients, clinically staged as T2-T3 by MRI or endoscopic/trans-rectal ultrasound • Rectal cancer staged as N0-N1 by MRI or EUS/TRUS • No metastatic lesion • Rectal tumor occupying less than half of the circumference • Tumor less than 5 cm on its largest dimension • Tumor located at less than 10 cm from the anal verge • Tumor penetration less than 5 mm in the mesorectal fat • Tumor accessible for brachytherapy • Lumen accessible for colonoscopy • Patient should be a suitable candidate for brachytherapy and chemotherapy • Older than 18 years of age • Adequate birth control measures in women of childbearing potential • Written informed consent
Critères d'exclusion	• Patients with previous pelvic radiation • Evidence of distant metastasis • Extension of malignant disease to the anal canal • Tumors staged as T4 • Tumors larger than 5 cm in length