



Essai Clinique

Généré le 15 mai 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	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Carole Richard
Coordonnateur	Nassima Taleb 514-890-8000 poste 10812
Statut	Actif en recrutement
Date d'activation	28-11-2023
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