Essai Clinique

Généré le 25 avr. 2024 à partir de

Titre	Chimioradiothérapie externe radicale chez les patients atteints d'un cancer rectal : une approche attentiste
Protocole ID	14-407 GEN
ClinicalTrials.gov ID	NCT03001362
Type(s) de cancer	Anus
Phase	Phase II
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Actif en recrutement
But étude	Patients with histologically proven adenocarcinoma of the rectum will receive pelvic radiotherapy to a dose of 45Gy in 25 fractions with a tumor boost to a dose of 9Gy in 5 fractions (thus total of 54Gy/30Fx to the primary tumor), combined with radio sensitizing chemotherapy. Patients will then be closely monitored, through endoscopy and imaging, for response to treatment and relapse. Salvage oncologic surgery to be offered if there is failure to achieve complete clinical response or in the event of a loco regional relapse.
Critères d'éligibilité	• Pelvic MRI defined disease (at least one of the following): • mesorectum involved or breached - includes involvement of adjacent organ (s) (T3-T4) • involvement of muscularis propria (T2) • extra-mural vascular invasion • tumour deposit within the mesorectum • one or more involved mesorectal lymph node • Patients are considered medically fit for oncologic resection • ECOG performance status 0 or 1 • No evidence of established metastatic disease (CT chest and abdomen) • Absolute neutrophil count >1.5x109/L; platelets >100x109/L, • Serum transaminase <3 x ULN; • Adequate renal function (Cockroft Gault estimation >50 mL/min) • Bilirubin <1.5 x ULN • Ability to comply with oral medication • Willingness and ability to give informed consent and comply with treatment and follow up schedule • Age 18 or over
Critères d'exclusion	• Previous radiotherapy to the pelvis (including brachytherapy) • Enlarged extramesorectal nodes • Uncontrolled cardiorespiratory comorbidity (includes patients with inadequately controlled angina or myocardial infarction within 6 months of randomisation) • T1N0 disease without extra-mural venous invasion • Unequivocal evidence of metastatic disease (includes resectable metastases) • Major impairment of bowel function without defunctioning stoma/ileostomy (baseline grade 3 diarrhoea or clinically significant faecal incontinence) • History of another malignancy within the last 5 years except successfully treated basal cell cancer of skin or carcinoma in situ of uterine cervix. • Known dihydropyrimidine dehydrogenase deficiency • Known Gilberts disease (hyperbilirubinaemia)

- Taking warfarin or phenytoin or sorivudine
- Gastrointestinal disorder which would interfere with oral therapy and its bioavailability
- Pregnant, lactating, or pre-menopausal women not using adequate contraception
- Unfit to receive any study treatment or subsequent surgical resection