Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	Étude de phase III examinant la RTSC guidée par imagerie (GI) p/r à la RTMI hypofractionnée GI dans le traitement du cancer de la prostate localisé à risque intermédiaire
Protocole ID	NRG-GU005
ClinicalTrials.gov ID	NCT03367702
Type(s) de cancer	Prostate
Phase	Phase III
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 Peter Vavassis
Coordonnateur	Véronique Tran 514-252-3400 poste 3227
Statut	Fermé
But étude	This randomized phase III trial studies how well stereotactic body radiation therapy works compared to intensity-modulated radiation therapy in treating patients with stage IIA-B prostate cancer. Radiation therapy uses high energy x-rays to kill tumor cells and shrink tumors. Stereotactic body radiation therapy is a specialized radiation therapy that sends x-rays directly to the tumor using smaller doses over several days and may cause less damage to normal tissue. Stereotactic body radiation therapy may work better in treating patients with prostate cancer.
Critères d'éligibilité	• Previously untreated localized adenocarcinoma of the prostate with the following clinical findings: • Clinical stage by digital rectal exam of either T1c or T2a/b (limited to one side of the gland); (American Joint Committee on Cancer [AJCC], version 7) or cT1a-c or 2a or 2b, stage group IIA or IIB (AJCC, version 8); both versions 7 and 8 staging should be recorded • Patients in active surveillance who elect to be treated are eligible if they meet protocol requirements • Stages T1a-T1b are eligible if patient underwent transurethral prostatic resection (TURP) previously Gleason score must be Gleason 7(3+4) with a PSA < 20 ng/mL, or Gleason 6(3+3) with a PSA > 10 ng/mL and < 20 ng/mL; (AJCC, version 7) or group grade 1 or 2, stage Group IIA or IIB (AJCC version 8) • If patient is receiving a 5-alpha reductase inhibitor at the time of enrollment the baseline PSA value will be assumed to be double the initial value and the medication should be discontinued but does not need to have a washout period to participate, to remain eligible a PSA drawn while still on the medicine must be: • < 10 ng/mL to remain eligible if Gleason 7(3+4) • Stratification level 1 if PSA < 5 ng/mL and level 2 if less than 10 ng/mL • > 5 ng/mL and less than 10 ng/mL for Gleason 6(3+3) • Stratification level 3 • Percent of submitted positive core biopsies must be < 50% of all sextants • NOTE: all cores from a targeted lesion will be counted as an N of 1 core for calculating percent positive cores in total • The prostate volume must be < 60 cc as reported at time of biopsy or by separate measure with ultrasound or other imaging modalities including magnetic resonance imaging (MRI) or computed tomography (CT) scan • History and physical including a digital rectal exam 60 days prior to registration • Eastern Cooperative Oncology Group (ECOG) performance status 0-1 60 days prior to registration

	• MRI of pelvis within 90 days prior to registration • Bone scan or sodium fluoride positron emission tomography (PET) scan within 90 days prior to registration • Charlson modified co-morbidity score =< 3 for patients under 60 and =< 4 for patients 60 and over 21 days prior to registration • International prostate symptom score (IPSS) of < 15 21 days prior to registration • The patient must provide study-specific informed consent prior to study entry • Willingness and ability to complete the Expanded Prostate Cancer Index Composite (EPIC-26) questionnaire • Completion of all items of the EPIC-26 which will be data entered at registration 60 days prior to registration • Only English, Spanish, and French-speaking patients are eligible to participate
Critères d'exclusion	• Definitive clinical or radiologic evidence of metastatic disease; no nodal involvement or evidence of metastatic disease allowed as defined by screening of the pelvis and a bone scan or sodium fluoride PET scan • Definitive T3 disease on MRI • Prior or current invasive malignancy with current evidence of active disease within the past 3 years • Prior systemic chemotherapy for the study cancer; note that prior chemotherapy for a different cancer is allowable; must be off treatment for at least 3 years; [applicable only to studies that incorporate systemic therapy] • Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields • The use of hormonal therapy is not allowed; if the patient in on a 5-alpha reductase inhibitor, then they should be stopped prior to treatment once enrolled onto the study; no washout period is required for this study to participate • Severe, active co-morbidity defined as follows: • Human immunodeficiency virus (HIV) positive with CD4 count < 200 cells/microliter; Note that patients who are HIV positive are eligible, provided they are under treatment with highly active antiretroviral therapy (HAART) and have a CD4 count >= 200 cells/microliter within 30 days prior to registration; Note also that HIV testing is not required for eligibility for this protocol • Hepatic insufficiency resulting in clinical jaundice and/or coagulation defects; note, however, that laboratory tests for liver function and coagulation parameters are not required for entry into this protocol; (patients on Coumadin or other blood thinning agents are eligible for this study) • Contraindication to MRI • Cardiac pacemaker or defibrillator • Surgically implanted electrical devices such as spinal stimulation devices or intracranial stimulation devices, cochlear implants, the presence of metallic foreign bodies in the orbits, and incompatible old mechanical heart valves and aneurysm clips