Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	Étude de phase III sur la radiothérapie hypofractionnée avec escalade de dose vs la radiothérapie pelvienne srtandard suivie de curithérapie d'appoint à forte dose pour les adénocarcinomes prostatiques à haut risque
Protocole ID	PCS VI
ClinicalTrials.gov ID	NCT02303327
Type(s) de cancer	Prostate
Phase	Phase III
Institution	CISSS DE L'OUTAOUAIS HOPITAL DE GATINEAU 909 Boulevard La Vérendrye, Gatineau, QC, J8P 7H2
Ville	Gatineau
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Statut	Fermé
But étude	In North America, the number of new cases of prostate cancer increases every year. Many efforts have been made to develop more efficient and safer curative treatments for high risk prostate cancer patients. This phase III clinical trial is designed to compare the safety of a standard pelvic external beam radiation therapy (EBRT) combined with a high dose rate brachytherapy (HDRB) boost (direct insertion of radiation source over a period of minutes via flexible needles temporarily inserted in the prostate) to a shorter course of hypofractionated dose escalation radiotherapy (larger radiation dose per daily treatment) in patients with high risk prostate cancer.
Critères d'éligibilité	• Histologically confirmed adenocarcinoma of the prostate diagnosed within 6 months prior to randomization, (if longer than 6 months, needs to be approved by the PI). • Clinical stage including at least one of the following: T3 or T4, Gleason Score > 8, and/ or Prostate-specific antigen (PSA) > 20 (ng/ml or µg/L). • Pelvic and para-aortic lymph nodes must be negative on CT scan or MRI of the abdomen and pelvis performed within 12 (recommended time limit, may exceed in certain cases) weeks prior to randomization. For patients who have started androgen suppression prior to randomization, CT or MRI may be done after start of therapy, provided it is done no more than 28 days following start of androgen suppression therapy (any lymph node appearing > 1.5 cm on CT or MRI must be histologically negative by either needle aspirate or lymph node dissection performed within 12 weeks prior to randomization). • Investigations, including chest x-ray (CXR is recommended and not mandatory) CT scan and bone scan (with radiographs of suspicious areas) have been performed within 12 weeks (recommended time limit) prior to randomization and are negative for metastases. For patients who have started androgen suppression prior to randomization, bone scan may be done up to and including 28 days after the commencement of therapy. • Patients will have had a PSA test done at the time of diagnosis. This PSA test could be repeated within 28 days prior to randomization. The PSA value used to confirm high risk disease and the value to be entered on the eligibility checklist must be the higher of these two values. These criteria will be the same regardless of whether or not the patient has initiated hormone therapy prior to randomization. • The patient may have received prior androgen suppression therapy provided that androgen suppression therapy commenced no more than 28 days prior to randomization. • The patient must not have received any cytotoxic anticancer therapy for prostate cancer prior to randomization. Patients may have received treatment with a 5-alpha-reductase inhibitor (e.g. Finasteride) for benign prostatic hypertrophy (BPH), which must have been discontinued prior to the randomization. • ECOG performance status must be 0 or 1.

	• Hematology and Biochemistry: Laboratory requirements have been done within 28-42 days prior to randomization: hemoglobin > 100 g/L, absolute Neutrophils > 1.5 x 109/L, platelets > 100 x 109/L, serum creatinine < 1.5 x ULN
Critères d'exclusion	• Patients with a history of other malignancies, except: non-melanoma skin cancer; or other solid tumours curatively treated with no evidence of disease for > 5 years. • The presence of small-cell or transitional-cell carcinoma in the biopsy specimen. • Patients who had previous chemotherapy for carcinoma of the prostate. • Patients who had prior surgical treatment for carcinoma of the prostate apart from trans-urethral resection, including bilateral orchiectomy. • Patients with any contraindication to pelvic radiotherapy: including, but not limited to, previous pelvic radiotherapy. Inflammatory bowel disease (at the discretion of the treating oncologist) or severe bladder irritability. • Patients with serious non malignant disease resulting in a life expectancy less than 3 years. • Other serious illness, psychiatric or medical condition that would not permit the patient to be managed according to the protocol including active uncontrolled infection and significant cardiac dysfunction. Patients with medical conditions that would contraindicate the treatment regimen outlined in the protocol [e.g. intake of study drugs]. • Known hypersensitivity to any protocol-indicated study medications. • Presence of bilateral hip replacement prostheses. • Patients with history of severe congestive heart failure will not be eligible. • Patients with congenital long QT syndrome or patients taking Class IA, Class III or Class IC anti-arrhythmic medications will require a cardiologist's evaluation prior to eligibility assessment. Patients with cardiovascular diseases can be included as long as the benefits of androgen deprivation therapy outweigh the potential risk of cardiovascular events.