Essai Clinique

Généré le 26 avr. 2025 à partir de

Titre	A Phase II Randomized Trial of Bicalutamide in Patients Receiving Intravesical BCG for Non-muscle Invasive Bladder Cancer
Protocole ID	BicaBCa
ClinicalTrials.gov ID	NCT05327647
Type(s) de cancer	Vessie/urothélial
Phase	Phase II
Type étude	Clinique
Médicament	Bicalutamide
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
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Investigateur principal	Dr Paul Toren
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Statut	Actif en recrutement
Date d'activation	25-05-2022
But étude	This is a phase II randomized controlled clinical trial comparing standard induction BCG versus bicalutamide and standard induction BCG among patients with non-muscle invasive bladder cancer. Bladder cancer is the second most common urological cancer after prostate cancer. Non-muscle invasive bladder cancer (NIMBC) is the most common form (~ 75%). The standard treatment involves the use of intravesical instillation of bacillus Calmette-Guérin (BCG). Nonetheless, 30-40% of the patients still relapse or progress. Clinical and laboratory research suggests that medications targeting the androgen receptor, such as bicalutamide, combined with the standard treatment with BCG may decrease the recurrence rate of NMIBC. The participants will be randomized to either the treatment with 1) daily intake of 150 mg bicalutamide for 3 months overlapping with the 6 cycles of intravesical instillations of BCG or 2) the standard of care of 6 cycles of intravesical instillation BCG . The participation to this this trial should last 36 months from the screening visit to the last follow-up visit.
Critères d'éligibilité	• Males, age 18 or greater. • Patients with histologically confirmed non-muscle invasive urothelial carcinoma. • Patients have been recommended for a course of intravesical BCG induction treatment by their urologist • Patients who received gemcitabine, epirubicin or mitomycin C instillations immediately post-operatively will be eligible for enrollment. • Patients with partners of child-bearing potential must agree to 2 acceptable forms of birth control and be continued for at least 3 months after study drug is discontinued.
Critères d'exclusion	• Patients who have received induction BCG therapy within the last 5 years will be ineligible for enrollment. • Patients who have received an induction course of intravesical chemotherapy within the last 5 years will be ineligible for enrollment. • Patients with a history of myocardial infarction or hospital admission for heart failure within the previous 12 months or who have unstable cardiovascular status will be ineligible for enrollment. • Patients who have uncontrolled hypertension (for our purposes, defined as those having a

systolic blood pressure > 160 documented on 2 occasions despite appropriate medical therapy) will similarly be ineligible.

- Patients with a history of venous thrombo-embolism (DVT/PE) within the past 3 years.
- Patients with a history of liver disease whose hepatic enzymes, alkaline phosphatase or bilirubin are greater than twice the upper limit of normal will be ineligible.
- Patients with kidney disease with an estimated glomerular filtration rate (eGFR) < 30 will be ineligible.
- Patients with neutropenia (< 3,000/μL) will be ineligible.
- Patients with clinical hypogonadism, those on androgen replacement therapy, or those with prostate cancer or other diseases treated with various forms of hormonal therapy will be ineligible for study enrollment. Patients receiving 5-alpha-reductase inhibitors will not be excluded.
- Patients who have undergone treatment for any malignancy other than bladder cancer within the past 2 years except for superficial non-melanoma skin cancers.
- Patients with prior history of prostate cancer treated by definitive local therapy > 5 years ago will only be eligible if they have had no clinical or biochemical evidence of recurrent prostate cancer.
- Patients taking an investigational drug within 3 weeks of enrollment into this study.
- Patients receiving or planning to receive coumadin therapy