

Essai Clinique Généré le 09 mai 2025 à partir de

Titre	Essai de phase II à répartition aléatoire évaluant le traitement trimodal avec ou sans traitement adjuvant par durvalumab pour traiter les patients atteints d'un cancer de la vessie à envahissement musculaire.
Protocole ID	BL13
ClinicalTrials.gov ID	<u>NCT03768570</u>
Type(s) de cancer	Vessie/urothélial
Phase	Phase II
Stade	Métastatique
Type étude	Traitement
Médicament	Durvalumab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
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Statut	Fermé
But étude	This study is looking at whether a type of immunotherapy drug called durvalumab can be safely administered after initial treatment received by a patient. Durvalumab has been tested in many different types of cancers. Durvalumab works by allowing the immune system to detect cancer and reactivate the immune response. This may help to slow down the growth of cancer or may cause cancer cells to die. It is unclear if the addition of durvalumab is beneficial in patients with bladder cancer who have completed surgery, radiotherapy and chemotherapy.
Critères d'éligibilité	 Histologic diagnosis of urothelial carcinoma of the bladder. Patients with mixed histology and focal differentiation are eligible but patients with pure small cell histology will be excluded. Stage T2-T4a NOM0 at time of diagnosis based on trans-urethral resection of bladder tumour, imaging, and/or bimanual examination under anesthesia. CT scan of the chest/abdomen/pelvis within 8 weeks from enrollment, showing no evidence of metastatic disease. Patients must be ≥ 18 years of age. Patients must have a life expectancy greater than 6 months. Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 and a body weight of > 30kg. Patients must have adequate hematologic reserve: Platelet count ≥ 75 x 10^9/L, Absolute neutrophils ≥ 1.0 x 10^9/L. Anemia will be corrected to minimum hemoglobin of 90 g/L with red cell transfusions, if necessary. Patients must have an estimated creatinine clearance (Cockcroft-Gault Equation) ≥ 30 ml/min. Patients must have a atom estimated creatinine clearance (Cockcroft-Gault Equation) ≥ 30 ml/min. Patients must have a tumour block from their primary tumour available and consent to release the block/cores/cut slides for correlative analyses (and the centre/pathologist must have agreed to the submission of the specimen(s). Patients have completed prior trimodality therapy (TMT) consisting of surgery, chemotherapy and radiation therapy treatment prior to enrollment. Patient should start treatment within 42

	 days after completion of TMT. Patients have completed transure thral resection prior to study enrollment. Patient may have completed up to 4 cycles of cisplatin-based neo-adjuvant chemotherapy. Adjuvant chemotherapy is not permitted. Patients will have received cisplatin, given intravenously during the radiation therapy. OR Patients may have received fluorouracil and mitomycin given intravenously once weekly or gemcitabline as an alternative to cisplatin during radiotherapy. The following are radiotherapy guidelines for patients treated on study. Patients will be treated to radical treatment doses using IMRT, VMAT or 4 field conformal techniques. Planning will be based on CT planning. IGRT is recommended during the radiotherapy treatment. Recognizing differences in usual radiotherapy doses used in the various participating countries and centres the following would be acceptable doses in this study. The bladder CTV will include the whole empty bladder and any extravesical extension. PTV expansion will be a minimum of 0.75 cm right, left and inferiorly, 1.5 cm Anteriorly and superiorly and 1 cm posteriorly. These minimum expansions are with Cone beam verification. For patients undergoing RT without image-guided verification 1.5 cm expansion in all directions is recommended. Acceptable doses for this study include: Bladder only: 64-66 Gy in 32-33 fractions over 6.5 weeks; 50-55 Gy in 20 fractions over 4 weeks. Pelvis and bladder: 45-46 Gy to pelvic nodes + 17-20 Gy bladder boost in 33-35 fractions over 6.5-7 wks [Note: minimal nodal dose] (fi used) is 44 Gy in 32f or 40 Gy in 20f] Patient s receiving concurrent bladder boost: pelvis dose 40 Gy and bladder dose 50 Gy given in 20 fractions over 4 weeks. Adaptive radiotherapy techniques would be acceptable. Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrollment in the trial to docume
Critères d'exclusion	 Pre-existing medical conditions precluding treatment. Pregnancy or lactating mothers. Received prior therapy with an anti-programmed cell death protein 1 (anti-PD-1), anti-PD-L1, including durvalumab anti-programmed cell death-ligand 2 (anti-PD-12), anti-CD137 (4-18B ligand, a member of the Tumour Necrosis Factor Receptor [TNFR] family), or anti-Cytotoxic T-lymphocyte-associated antigen-4 (anti-CTLA-4) antibody (including ipilimumab or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways). Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease (e.g. colitis or Crohn's disease), diverticulitis with the exception of diverticulosis, celiac disease (controlled by diet alone) or other serious gastrointestinal chronic conditions associated with diarrhea), systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome (granulomatosis with polyangilis), rheumatoid arthritis, hypophysitis, uveitis, etc., within the past 3 years prior to the start of treatment. The following are exceptions to this criterion Patients with alopecia; Patients with hypothyroidism (e.g. following Hashimoto syndrome) stable on hormone replacement; Any chronic skin condition that does not require systemic therapy. Patients with active or uncontrolled intercurrent illness including, but not limited to: cardiac dysfunction (symptomatic congestive heart failure, uncontrolled hypertension, unstable angina pectoris, cardiac arrhythmia); active peptic ulcer disease or gastritis; active bleeding diatheses; psychiatric illness/social situations that would limit compliance with study requirements or compromise the ability of the subject to give written informed consent; known active hepatitis B infection (positive HBV 1/2 antibodies); known active hepatitis B infection (positive HBV surface antigen (HBsAg). Patients with a past or r

 Protocol. Live attenuated vaccination administered within 30 days prior to randomization.