Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	Étude de phase III à répartition aléatoire portant sur la cystectomie en association avec le pembrolizumab périopératoire par rapport à la cystectomie en monothérapie chez des participants non admissibles au cisplatine atteints d'un cancer de la vessie avec envahissement musculaire
Protocole ID	MK-3475-905 (KEYNOTE-905)
ClinicalTrials.gov ID	NCT03924895
Type(s) de cancer	Vessie/urothélial
Phase	Phase III
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Ramy Saleh
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Statut	Fermé
Date d'activation	01-12-2022
But étude	A global, randomized phase III study to evaluate perioperative pembrolizumab with radical cystectomy + pelvic lymph node dissection (RC+PLND) versus RC+PLND alone in cisplatin-ineligible patients with muscle-invasive bladder cancer (MIBC).
Critères d'éligibilité	• Histologically confirmed diagnosis of muscle invasive bladder cancer (T2-T4aN0M0) with predominant (≥50%) urothelial histology. Participants with mixed histology are eligible provided the urothelial component is ≥50%. Urothelial carcinomas not originating from the bladder are not eligible. Participants whose tumors contain any neuroendocrine component are not eligible. • Clinically non-metastatic bladder cancer determined by imaging • Eligible for radical cystectomy (RC) + pelvic lymph node dissection (PLND), and agreement to undergo curative intent standard RC + PLND (including prostatectomy if applicable) • Ineligible for treatment with cisplatin, as defined by meeting at least one of the following criteria: • Impaired renal function with measured or calculated CrCl 30 to 59 mL/min • Eastern Cooperative Oncology Group (ECOG) Performance Status 2 • Common Terminology Criteria for Adverse Events (CTCAE) v.4 Grade ≥2 audiometric hearing loss • CTCAE v.4 Grade ≥2 peripheral neuropathy • New York Heart Association (NYHA) Class III heart failure • Transurethral resection (TUR) of a bladder tumor that is submitted and adequate for evaluation of histology, muscle invasion and PD-L1 status • ECOG performance status of 0, 1, or 2 • Adequate organ function

Critères d'exclusion	• Known additional non-urothelial malignancy that is progressing or has required active treatment ≤3 years of study randomization, with certain exceptions • Received any prior systemic anti-neoplastic treatment for muscle-invasive bladder cancer (MIBC) • Received prior therapy with a anti-programmed cell death protein 1 (PD-1), anti-programmed death-ligand 1 (PD-L1), or anti-programmed cell death 1 ligand 2 (PD-L2), or with an agent directed to another stimulatory or co-inhibitory T-cell receptor • Received prior systemic anti-cancer therapy including investigational agents within 3 years prior to randomization • Received any prior radiotherapy to the bladder • Received a live vaccine within 30 days prior to the first dose of study drug • Current participation in or participation in a study of an investigational agent or use of an investigational device within 4 weeks prior to the first dose of study intervention • Diagnosis of immunodeficiency or receipt of chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study drug • Hypersensitivity to monoclonal antibodies (including pembrolizumab) and/or any of their excipients • Active autoimmune disease that has required systemic therapy in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic therapy and is allowed. • History of (non-infectious) pneumonitis that required steroids, or current pneumonitis. • Active infection requiring systemic therapy