Essai Clinique

Généré le 27 avr. 2024 à partir de

Titre	Radiothérapie des Cordes Vocales vs. du Larynx Entier pour le Traitement du Cancers Glottiques de Stade Précoce (VOCAL): Une Étude Bayésienne Multicentrique Randomisée de Phase II
Protocole ID	VOCAL
ClinicalTrials.gov ID	NCT03759431
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Traitement
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	Montréal
Investigateur principal	Dre Houda Bahig
Coordonnateur	Diane Trudel 514-890-8000 poste 11181
Statut	Actif en recrutement
Date d'activation	02-10-2018
But étude	This is a multicentrer, randomized Bayesian Phase II trial for patients with early stage (T1N0) glottic squamous cell carcinoma treated with radical radiotherapy. The primary objective is to assess the non-inferiority of local control achieved with vocal-cord only radiotherapy (VC-RT) compared to complete larynx radiotherapy (CL-RT) in T1N0 glottic laryngeal squamous cell cancer, measured at 2-years after treatment. Secondary outcomes include overall survival, as well as voice impairment, dysphagia and quality of life, measured respectively by the voice handicap index -10 (VHI-10), the MD Anderson Dysphagia Inventory (MDADI) and the MD Anderson Symptom Inventory- Head and Neck module (MDASI-HN). Patients will be randomized in a 1:3 ratio to CL-RT (39 patients) and VC-RT (116 patients) arms. There will be stratification by tumor stage (T1a/T1b) and by institution. An interim analysis is planned after the first 55 patients enrolled on the experimental arm have a 6-month follow-up.
Critères d'éligibilité	• Stage T1a-b N0 of the true vocal cords planned for definitive RT • Patient not candidate for laser surgery or declined laser surgery • Biopsy-confirmed squamous cell carcinoma, including verrucous carcinoma • Eastern Cooperative Oncology Group performance status 0-2 • Ability to provide written informed consent.
Critères d'exclusion	• Previous irradiation of the head and neck (HNC) region • Pregnancy or breastfeeding • Any medical condition that represents, in the opinion of the investigator, a contraindication to radiotherapy or would prevent follow-up after radiotherapy. • Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 2 years.