Essai Clinique

Généré le 21 mai 2024 à partir de

Titre	SPECT-CT Guided ELEctive Contralateral Neck Treatment for Patients With Lateralized Oropharyngeal Cancer. A Phase III Randomized Controlled Trial
Protocole ID	HN11 (SELECT)
ClinicalTrials.gov ID	NCT05451004
Type(s) de cancer	ORL
Phase	Phase III
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dre Isabelle Gauthier
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Statut	Actif en recrutement
Date d'activation	19-10-2023
But étude	This study is being done to answer the following question: Is the chance of cancer spreading or returning the same if radiotherapy to the neck is guided, by using a special imaging study called lymph node mapping (lymphatic mapping) Single Photon Emission Computed Tomography (SPECT-CT), compared to the usual treatment when radiotherapy is given to both sides of the neck?

Critères d'éligibilité	• Patients with pathologically proven diagnosis of lateralized OPC (tonsil, tongue base, soft palate, or pharyngeal wall) not involving or crossing midline.
	• HPV positive or negative (by p16 immunohistochemistry).
	• Clinical stage T1-3 M0 (UICC/AJCC TNM 8th Edition). Nodal involvement may include no nodes or single or multiple ipsilateral lymph nodes (largest ≤6cm in maximum diameter)
	• Radiological investigations within 8 weeks of registration:
	  • CT or MRI of the neck (with head imaging as indicated);
	  • PET-CT scan
	  • Chest CT scan
	• Planned definitive RT or CRT with bilateral neck RT (patients planned for unilateral neck RT are excluded).
	• Intent to deliver concurrent chemotherapy or not must be known at the time of randomization. As this is a pragmatic trial, even patients who are not candidates for systemic therapy will be eligible for participation.
	• Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.
	• Willing to complete the quality of life and/or health utility questionnaire, if sufficiently fluent in available language(s).
	• Informed consent prior to registration
	• Accessible for treatment and follow-up.
	• Commencement of definitive RT within 28 days (+ 14 days) of randomization.
	• Injection procedure for lymphatic mapping may be performed in the nuclear medicine, ambulatory clinic, or operating room setting
	• Women/men of childbearing potential must have agreed to use a highly effective contraceptive method
	• Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.
	• Patient must consent to provision of, and investigator(s) must confirm location and commitment to obtain a representation of formalin fixed paraffin block of non-cytology tumour tissue in order that the specific correlative marker assays

Critères d'exclusion	• T1-T2 cancers isolated to the tonsil fossa (i.e. without any soft palate, tongue base, posterior pharyngeal wall or posterior tonsil pillar involvement) with no involved lymph nodes or with a single ipsilateral node < 3 cm without extranodal extension.
	• Tonsil or tongue base primary cancer who have previously undergone diagnostic palatine or lingual tonsillectomy with either complete excision or with no clinically apparent residual disease
	• Previous head and neck cancer or multiple synchronous primary head and neck cancers
	• Previous induction or neo-adjuvant chemotherapy.
	• Previous radiation therapy to the head and neck or comprehensive neck dissection of at least 3 levels on either side (due to potential for disrupted lymphatic channels and drainage pathways). Patients who have had excisional biopsies of involved lymph nodes are eligible
	• Radiotracer allergy
	• Severe, active co-morbidity including any of the following:
	  • Chronic Obstructive Pulmonary Disease or other pulmonary illness requiring hospitalization within 30 days of registration
	  • Unstable angina and/or congestive heart failure requiring hospitalization within the 30 days of registration
	  • Acute myocardial infarction within 30 days of study registration
	  • Diseases precluding RT (e.g. scleroderma)