Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	Preservation of Swallowing in Resected Oral Cavity Squamous Cell Carcinoma: Examining Radiation Volume Effects: A Randomized Trial
Protocole ID	PRESERVE
ClinicalTrials.gov ID	NCT03997643
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Clinique
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Houda Bahig
Coordonnateur	Mom Phat 514-890-8000 poste 11171
Statut	Actif en recrutement
But étude	The goal of this randomized treatment study is to formally compare quality of life in patients with at least one pN0 hemi-neck after resection of a squamous cell carcinoma of the oral cavity treated with a primary radiation therapy versus a secondary targeted radiation therapy approach, to provide a high level of evidence to guide the selection of treatment options.
Critères d'éligibilité	• Willing to provide informed consent • ECOG performance status 0-2 • Histologically confirmed, resected oral cavity squamous cell carcinoma with at least ipsilateral selective neck disection • Patient has pathological features that are indications for PORT: positive or close (≤ 3 mm) margin, presence of LVI or PNU, pT3 or pT4 disease, positive lymph nodes, and PORT is recommended by treating physician • Pathologically lympth node negative in at least one dissected hemi-neck with at least 10 nodes recovered in each pN0 hemi-neck
Critères d'exclusion	• Serious medical comorbidities or other contraindications to radiotherapy • Prior history of head and neck cancer within 5 years • Any other active invasive malignancy, except non-melanotic skin cancers • Prior head and neck radiation at any time • Prior oncologic head and neck surgery in the oral cavity or neck • Metastatic disease • Locoregional disease recurrence identified following surgical resection but prior to the start of radiotherapy • Inability to attend full course of radio therapy or follow-up visits • Unable or unwilling to complete QoL questionnaires • Pregnant or lactating women