Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	Adaptive RadioTherapy for Locally Advanced OroPharynx Cancer (ART-OPC) A Phase II Randomized Trial
Protocole ID	ART-OPC
ClinicalTrials.gov ID	NCT04901234
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	Silvine Benth 514-890-8000
Statut	Actif en recrutement
But étude	This is a phase II randomized trial, where patients with histologically proven squamous cell carcinoma of oropharynx that have primary tumor (T3 - T4) in place, treated with curative intent chemoradiation, will be randomized to systematic mid-treatment MRI-based radiotherapy adaptation vs. standard of care. The primary objective is to compare patient-rated dysphagia (as assessed by the MD Anderson Dysphagia Inventory composite score at 6 months post-treatment in patients undergoing routine mid-treatment MR-guided radiotherapy adaptation vs. in patients receiving the current standard of care.
Critères d'éligibilité	• Age ≥18 years • Ability to provide written informed consent. • Stage T3-T4N0-3 as per AJCC 8th edition • Eastern Cooperative Oncology Group (ECOG) performance status 0-2. • Biopsy proven diagnosis of squamous cell carcinoma of the oropharynx. • Planned for curative radiotherapy +/- chemotherapy • For females of child-bearing age, a negative pregnancy test • Patients treated with induction chemotherapy can be included if they have residual tumor in place.
Critères d'exclusion	• Previous irradiation of the head and neck (HNC) region, excluding superficial radiation therapy for non-melanomatous skin cancer • Previous surgery of the HNC region (except for incisional or excisional biopsies) • Pregnancy or breastfeeding • Connective tissue disease • Any medical condition that could, in the opinion of the investigator, prevent follow-up after radiotherapy. • Patients with contra-indications to MRI will be excluded.