Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	Stereotactic Ablative Radiotherapy for Oligo-Progressive Disease REfractory to Systemic Therapy in Head and Neck Cancer: A Phase II Randomized Trial
Protocole ID	Suppress-HNC
ClinicalTrials.gov ID	NCT04989725
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Clinique
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
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Statut	Actif en recrutement
But étude	A registry-based randomized phase II trial. A total of 46 patients with metastatic head and neck cancer on systemic therapy with oligoprogression to 1-5 extracranial lesions will be randomized using a 1:1 ratio to standard of care (begin next-line systemic therapy, best supportive care, continue current systemic line, based on treating physician decision) vs. receive stereotactic ablative radiotherapy to all oligoprogressive lesions while continuing their current systemic therapy.
Critères d'éligibilité	• Age ≥18 years • Biopsy proven HNSCC (oropharynx, oral cavity, nasopharynx, sinonasal, larynx or hypopharynx) • Metastatic HNSCC, with pathological or radiological proof of metastasis • Ability to provide written informed consent • Eastern Cooperative Oncology Group (ECOG) performance status 0-2 • Progressive disease while on systemic treatment (any line), defined as per RECIST criteria 1.1 on CT metrics as a greater than 20% increase in the sum measurement of lesions, non-target unequivocal progressive disease or a new lesion on CT. • Oligoprogression to 1-5 extracranial lesions ≤ 5cm and involving ≤ 3 organs. Progression at the primary tumor site should be counted within the total of 5 lesions. For patients with lymph node metastases, each node is counted as one site of metastasis. • All sites of disease can, in the opinion of the investigator, be safely treated and targetable with SABR (taking into account prior local therapy, organ function and underlying medical condition such as inflammatory bowel disease, pulmonary fibrosis, etc.) • Patients with prior metastases that have been treated with ablative therapies (e.g. radiotherapy, surgery or radiofrequency ablation) before their current line of systemic therapy, are eligible.
Critères d'exclusion	• Pregnancy or breastfeeding • Any medical condition that could, in the opinion of the investigator, preclude radiotherapy or prevent follow-up after radiotherapy. • Presence of spinal cord compression • Metastatic disease that invades the GI tract (including esophagus, stomach, small or large bowel