Essai Clinique

Généré le 06 mai 2024 à partir de

Titre	A Randomized Trial of Treatment De-Escalation for HPV-Associated Oropharyngeal Squamous Cell Carcinoma: Radiotherapy vs. Trans-Oral Surgery (ORATOR II)
Protocole ID	ORATOR2
ClinicalTrials.gov ID	NCT03210103
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Traitement
Médicament	Radiothérapie vs chirurgie
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
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Statut	Fermé
But étude	The goal of this randomized treatment de-escalation study is to formally compare outcomes in HPV related oropharyngeal cancer tumors treated with a primary radiotherapy versus a primary surgical approach, to provide a high level of evidence to guide the selection of treatment options for a subsequent phase III trial.
Critères d'éligibilité	• Age 18 years or older • willing to provide informed consent • ECOG performance status 0-2 • Histologically confirmed squamous cell carcinoma • P16 positive, or HPV positive • Primary tumor site in the oropharynx (includes tonsil, soft palate, base of tongue, walls of oropharynx) • Eligible for curative intent treatment, with likely negative resection margins at surgery. For patients where adequate transoral access is in question, they will first undergo an examination under anesthesia prior to randomization to ensure adequate exposure can be obtained. • Smokers and non-smokers are included. Patients will be stratified by ,<10 pack years smoking history versus > or equal to 10 pack years. • Tumor stage (AJCC 8th edition): T1 or T2 • Nodal stage (AJCC 8th edition): N0, N1, or N2 • For patients who may require chemotherapy (ie, patients with multiple lymph nodes positive or a single node more than 3 cm in size, in any plane, CBC/differential within 4 weeks prior to randomization with adequate bone marrow function, hepatic, and renal function defined as: Hemoglobin ≥ 80 g/L; Absolute neutrophil count ≥ 1.5 x 10 9/L, platelets ≥ 100 x 10 9/L, bilirubin ≤ 35 umol/L, AST or ALT ≤ 3 x the upper limit of normal; serum creatinine ≤ 130 umol/L or creatinine clearance ≥ 50 ml/min • patients assessed at head and neck multidisciplinary clinic (with assessment by radiation oncologist and surgeon) and presented at multidisciplinary tumor board prior to randomization

Critères d'exclusion	• unambiguous clinical or radiological evidence of extranodaal extension on pre-treatment imaging. This includes the presence of matted notes, defined as 3 or more nodes that are abutting with loss of intervening fat planes • Serious medical comorbidities or other contraindications to radiotherapy, chemotherapy or surgery • prior history of head and neck cancer within 5 years • prior head and neck radiation at any time • metastatic disease • inability to attend full course of radiotherapy or follow up visits • prior invasive malignant disease unless disease-free for at least 5 years or more, with the exception of non-melanoma skin cancer • pregnant or lactating women