Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	Essai de phase II comportant un groupe unique de traitement facultatif par radiothérapie à dose dégressive en fonction du volume (EVADER) chez les patients atteints d'un carcinome épidermoïde oropharyngé lié au VPH comportant un faible risque
Protocole ID	HN.10
ClinicalTrials.gov ID	NCT03822897
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Traitement
Médicament	Radiothérapie + Cisplatine
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE H HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	Sherbrooke
Investigateur principal	Dr Chang Shu-Wang
Coordonnateur	Sophie Couture 819-346-1110 poste 14311
Statut	Fermé
But étude	The purpose of this study is to find out whether radiotherapy to some of the lymph node areas can be safely omitted to decrease side effects without increasing the risk of the tumour coming back.
Critères d'éligibilité	• Patients with pathologically proven diagnosis of HPV-related OPSCC • Clinical stage T1-3 N0-1 M0 (UICC/AJCC 8th Ed.) • Patients must be eligible for definitive RT or CRT • Must be ≥ 18 years of age • Must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 • Patient is able (i.e. sufficiently fluent) and willing to complete the quality of life and health economics questionnaires in either English or French • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrolment in the trial to document their willingness to participate • Patients must be accessible for treatment and follow up. Patients registered on this trial must be treated and followed at the participating centre • In accordance with CCTG policy, protocol treatment is to begin within 3 weeks of patient registration • Women/men of childbearing potential must have agreed to use a highly effective contraceptive method • The following radiological investigations must be done within 8 weeks of randomization: CT or MR of head and neck (MRI is recommended for base-of-tongue primary tumors); PET-CT scan. • Patient must consent to provision of and investigator must confirm adequacy of non-cytology tissue samples and confirm access to and agree to submit within 4 weeks of randomization to the CCTG Central Tumour Bank, a representative formalin fix paraffin block of non-cytology tumour tissue in order that the specific correlative marker assays described may be conducted. • Patient must consent to provision of samples of blood and plasma (for circulating cell free DNA) in order that the specific correlative marker assays described may be conducted. • Patients with 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.

Critères d'exclusion	• Previous chemotherapy or radiotherapy treatment for head and neck cancer