HPV DNA-Guided Radiotherapy De-intensification of Head and Neck Squamous Cell Carcinoma

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Provision of signed and dated informed consent form 2. Stated willingness to comply with all study procedures and availability for the duration of the study 3. Male or female, ≥ 18 years of age 4. Pathologically proven diagnosis of squamous cell carcinoma of the oropharynx of any AJCC 8th edition stage. 5. Eligible for and planning to receive definitive treatment or adjuvant treatment with radiotherapy. 6. Participants who are receiving concurrent systemic anticancer therapy (e.g. chemotherapy or immunotherapy) for oropharyngeal cancer are eligible. 1. For participants with T1-2 and N0 disease, chemotherapy is not required for eligibility. Participants may or may not receive chemotherapy per physician discretion. 2. For participants with T3-4 and/or N+ disease, chemotherapy is required for eligibility. 7. Participants may receive investigational agents with prior approval from the Principal Investigator. 8. ECOG Performance Status of 0-2. 9. p16 positive HPV as determined by NavDx and immunohistochemistry 10. For females of reproductive potential: agreement to use adequate contraception during radiation treatment and for 6 months (or more if applicable based on other medications) after the end of radiation treatment.

Exclusion Criteria:

1. Evidence of distant metastatic disease 2. Prior history of radiotherapy to the head and/or neck 3. Had surgery for oropharyngeal cancer within 8 months of enrollment unless it was an incomplete oncologic surgery. Participant is eligible if the gross tumor was not completely removed. 4. Diagnosis of T3-4 and/or N+ disease with no plans to receive concurrent chemotherapy. 5. Diagnosis of a current or prior invasive malignancy (except non-melanoma skin cancer) unless the participant has been disease free for at least 3 years. 6. Participant is a prisoner 7. Known contraindications to head and neck radiation therapy such as ataxia telangiectasia or scleroderma. 8. Pregnancy or lactation 9. Active or severe co-morbidities as defined by the following: 1. Unstable angina and/or congestive heart failure requiring hospitalization up to 180 days before registration 2. Transmural myocardial infarction up to 180 days before registration 3. Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration 4. Chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration 5. Hepatic insufficiency as determined by the treating clinician resulting in clinical jaundice and/or coagulation effects or severe liver dysfunction. 6. Acquired immune deficiency syndrome (AIDS) based upon current CDC definition. The need to exclude patients with AIDS from this protocol is necessary because the treatments involved in this protocol may be slightly immunosuppressive. Protocol-specific requirements may also exclude immuno-compromised patients. 10. Tobacco smoking history of 10 pack years or greater, or ≥ 20 pack years if smoking cessation occurred at least 1 year prior to enrollment 11. Current use of antineoplastic drugs for other malignancies.

Conditions & Interventions

Interventions:
RADIATION: Radiation Therapy
Conditions:
Squamous Cell Carcinoma of the Oropharynx
Keywords:
Radiation Therapy, Radiotherapy, Head Cancer, Neck Cancer, Low Dose Radiation, HPV

More Information

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