

# Radiation Therapy With or Without Cisplatin in Treating Patients With Stage III-IVA Squamous Cell Carcinoma of the Head and Neck Who Have Undergone Surgery

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

\* PRE-REGISTRATION (STEP 0) \* Pathologically proven diagnosis of squamous cell carcinoma (including variants such as verrucous carcinoma, spindle cell carcinoma, carcinoma not otherwise specified \[NOS\]) of the head/neck (oral cavity, oropharynx, hypopharynx or larynx); pathologic stage III or IVA (American Joint Committee on Cancer \[AJCC\] 8): T3-T4a, N0-3, M0 or T1-T2, N1-3, M0 \* Patient has undergone total resection of the primary tumor with curative intent \* NOTE: Patient is to be pre-registered to screening (Step 0) and tissue submitted to Foundation Medicine as soon as possible after surgery in order to meet the 8 week deadline to register the patient to Step 1 after surgery; full assay minimum turn-around time is 17-24 days \* For oropharynx primary tumors, the patient must have negative human papillomavirus (HPV) status of the tumor as determined by p16 protein expression using immunohistochemistry (IHC) \* Patients with, per the operative and/or pathology report, positive margin(s) (tumor present at the cut or inked edge of the tumor) which is not superceded by an additional margin of tumor-negative tissue, nodal extracapsular extension, and/or gross residual disease after surgery are not eligible \* A paraffin-embedded surgical tumor tissue specimen has been located is available for shipment to Foundation Medicine, Inc. following pre-registration \* NOTE: Complete the EA3132-specific FoundationOne requisition form \* Patients with a history of a curatively treated malignancy must be disease-free for at least two years except for carcinoma in situ of cervix and/or non-melanomatous skin cancer; patients must not have received chemotherapy or investigational therapy within two years of surgical resection of the primary tumor \* Patient must not have had previous irradiation to the head and neck that would result in overlap in radiation fields for the current disease \* Patients with recurrent disease or multiple primaries are ineligible \* RANDOMIZATION (STEP 1) \* NOTE: Patient must meet all eligibility criteria outlined in pre-registration; patient may not be randomized until site has been notified that the central determination of p53 mutation status of the surgical tumor tissue has been completed and site has been notified of assay completion \* Per the operative report, the gross total resection of the primary tumor with curative intent was completed within 8 weeks prior to randomization \* The patient must have the following assessments done =< 8 weeks prior to randomization: \* Examination by a head and neck surgeon \* Chest x-ray (or chest computed tomography \[CT\] scan or CT/positron emission tomography \[PET\] of the chest or magnetic resonance imaging \[MRI\]) to rule out distant metastatic disease \* Patient has Eastern Cooperative Oncology Group (ECOG) performance status 0-1 within 2 weeks prior to randomization \* Women must not be pregnant or breast-feeding; females of childbearing potential must have a blood or urine study within 2 weeks prior to randomization to rule out pregnancy; a female of childbearing potential is any woman, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has not undergone a hysterectomy or bilateral oophorectomy; or 2) has not been naturally postmenopausal for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) \* Women of childbearing potential and sexually active males must be strongly advised to use an accepted and effective method of contraception or to abstain from sexual intercourse for the duration of their participation in the study and until 60 days from the last study treatment \* Absolute neutrophil count  $\geq 1,500/\text{mm}^3$  within 4 weeks prior to randomization \* Platelets  $\geq 100,000/\text{mm}^3$  within 4 weeks prior to randomization \* Total bilirubin  $\leq$  the upper limit of normal (ULN) within 4 weeks prior to randomization \* Calculated creatinine clearance must be  $\geq 60$  ml/min using the Cockcroft-Gault formula within 4 weeks prior to randomization \* Patient must not have an intercurrent illness likely to interfere with protocol therapy

## Conditions & Interventions

### Interventions:

DRUG: Cisplatin, RADIATION: Intensity-Modulated Radiation Therapy, OTHER: Laboratory Biomarker Analysis

### Conditions:

Head and Neck Squamous Cell Carcinoma, Hypopharyngeal Squamous Cell Carcinoma, Laryngeal Squamous Cell Carcinoma, Laryngeal Squamous Cell Carcinoma, Spindle Cell Variant, Lip and Oral Cavity Squamous Cell Carcinoma, p16INK4a Negative Oropharyngeal Squamous Cell Carcinoma, Stage III Hypopharyngeal Carcinoma AJCC v8, Stage III Laryngeal Cancer AJCC v8, Stage III Lip and Oral Cavity Cancer AJCC v8, Stage III Oral Cavity Verrucous Carcinoma, Stage III Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage IVA Hypopharyngeal Carcinoma AJCC v8, Stage IVA Laryngeal Cancer AJCC v8, Stage IVA Lip and Oral Cavity Cancer AJCC v8, Stage IVA Oral Cavity Verrucous Carcinoma, Stage IVA Oropharyngeal (p16-Negative) Carcinoma AJCC v8

## More Information

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**Phase:** PHASE2

**IRB**

**Number:** HM20012856

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