

For Patients with SCCHN

EA3132 Available Through ECOG-ACRIN Cancer Research Group

Phase II Randomized Trial of Radiotherapy with or without Cisplatin for Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN) with TP53 Sequencing

Patient Population

See Section 3.0 for Complete Eligibility Details

Pre-Registration (Step 0):

- Age \geq 18 years
- Pathologically proven diagnosis of squamous cell carcinoma (including variants such as verrucous carcinoma, spindle cell carcinoma, carcinoma NOS) of the head/neck (oral cavity, oropharynx, hypopharynx or larynx); pathologic stage III or IVA (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: submit tissue ASAP after surgery in order to meet the 8 week deadline for Step 1 registration; full assay minimum turnaround time is 17-24 days)
- For oropharynx primary tumors, patient must have negative HPV status of the tumor as determined by p16 protein expression using IHC
- No positive margins (not superceded by an additional margin of tumor-negative tissue), nodal extracapsular extension, and/or gross residual disease post surgery
- Patients with a history of curatively treated malignancy must be disease-free for at least 2 years (exceptions for carcinoma in situ of cervix/non-melanomatous skin cancer); must not have received chemotherapy/ investigational therapy within 2 years of surgical resection of the primary tumor
- No previous irradiation to the H&N that would result in overlap in radiation fields for the current disease
- No patients with recurrent disease or multiple primaries

Randomization (Step 1): Site must be notified that the central determination of p53 mutation status of the surgical tumor tissue has been completed/assay has been completed

- The gross total resection of the primary tumor with curative intent was completed within 8 weeks prior to randomization; must have an exam by a H&N surgeon, chest x-ray (or chest CT or CT/PET of the chest or MRI) within 8 weeks of randomization
- ECOG PS 0-1 and adequate lab values

Treatment Plan

See Section 5.0 for Complete Treatment Details

Administration Schedule (Arms A and B):

- Protocol treatment must begin within 5 working days after registration and randomization to adjuvant treatment arm
- IMRT is mandatory; use of IGRT is optional (margin reduction is not permitted even when IGRT is used)
- The prescribed radiotherapy dose will be 60 Gy in 2 Gy once-daily fractions (total of 30 fractions)
 - ◇ Radiotherapy should begin on a Monday, Tuesday, or Wednesday and be completed as SOC according to institutional practices
 - ◇ Treatment of PTV60 followed by a 6 Gy boost is not permitted
- Arm B- Patients will receive cisplatin 40 mg/m² administered intravenously over 1-2 hours once a week for 6 weeks
 - ◇ Use actual body weight for all patients
 - ◇ Patients must receive vigorous hydration and diuresis (see protocol for pre-medications)

Technical Factors:

- All patients will be treated with IMRT using megavoltage photon radiation
- All therapy units used must have their calibrations verified by IROC Houston (RPC)
- Credentialing is required for IMRT

Localization, Simulation, and Immobilization:

- Patients must have an immobilization device for the head and neck made prior to the treatment planning CT scan
- The treatment planning CT scan can be performed with or without IV contrast
- Slice thickness should be \leq 3 mm
- IGRT is recommended; weekly verification imaging is required

Study Chair:

Robert L. Ferris, MD,
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Co-Chair:

Christine H. Chung, MD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) <https://open.ctsu.org>

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)

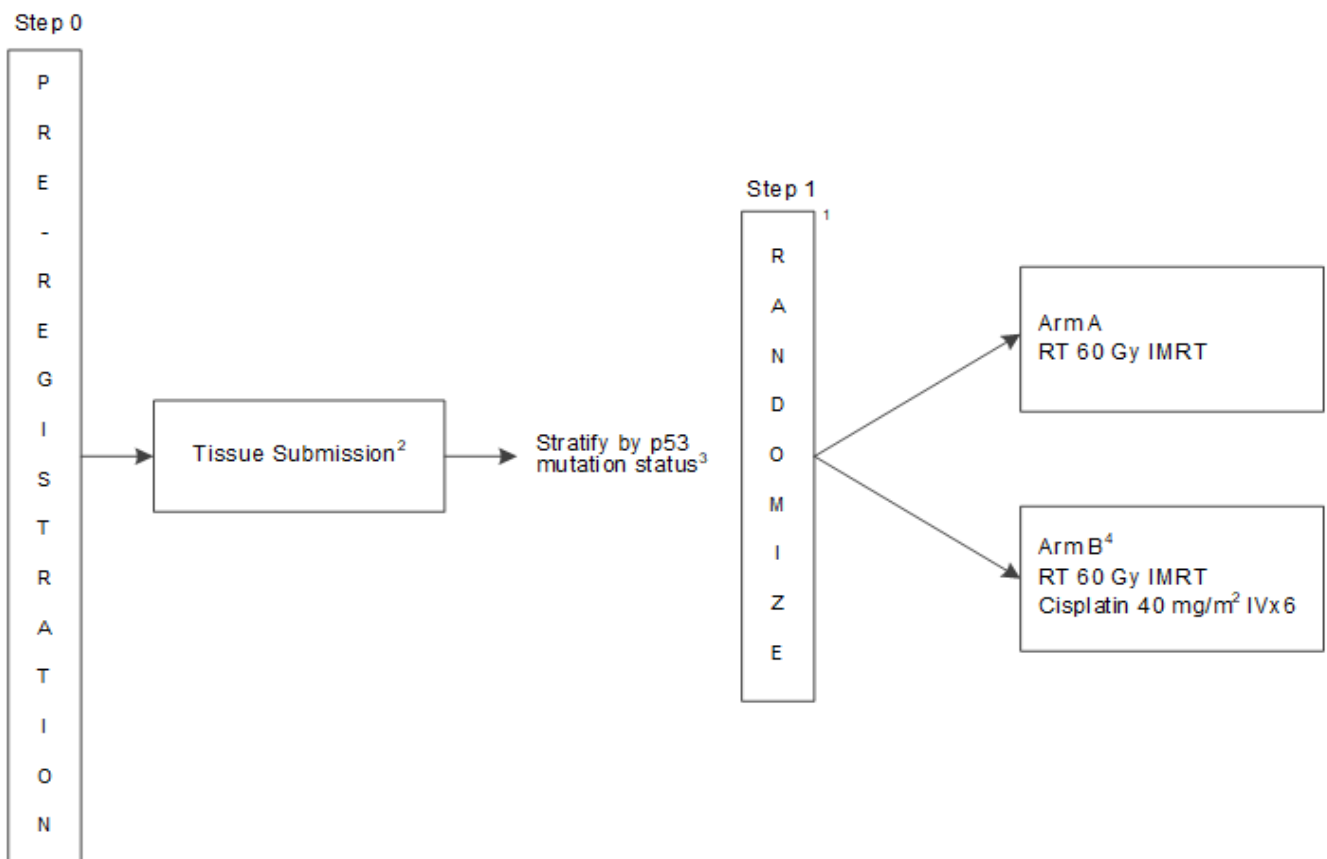
Please Enroll Your Eligible Patients!

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Schema



Accrual Goal = Step 0: 320-345

1. Registration to treatment (Step 1) must occur within 8 weeks of resection surgery. Patient is to be registered to screening (Step 0) and tissue submitted to Foundation Medicine (per Appendix I) as soon as possible after surgery in order to meet this deadline.
2. Submission to Foundation Medicine for Foundation One™ Assay + p53 mutation status. Enter Foundation Medicine study number "RAP-CLT-16023 EA3132" on the FoundationOne requisition form when submitting samples for screening.
3. Randomization will be stratified as follows:
 - disruptive p53 mutation;
 - non-disruptive p53 mutation;
 - p53 wild type.
4. Cisplatin 40mg/m² is given weekly X 6 during concurrent radiation (60GY) standard fractionation at 2Gy/day