NCI National Clinical Trials Network

EA3191

ECOG-ACRIN cancer research group

For Patients with Head and Neck Squamous Cell Carcinoma

EA3191 Available Through ECOG-ACRIN Cancer Research Group

A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab after Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features

Patient Population

See Section 3.0 for Complete Eligibility Details

- 18-79 years of age, ECOG PS 0-1, and adequate lab values
- Must have locoregionally recurrent or second primary HNSCC (oral cavity, oropharynx, larynx, hypopharynx) in a previously radiated field
- Must have undergone surgery with gross total resection and must be randomized within 8 weeks of surgery
- Must have high risk disease defined per protocol
- Must have a PD-L1 CPS ≥ 1 (in a CLIA laboratory)
- Must have had prior radiation to the area of recurrent/ second primary tumor (defined per protocol); completed a minimum of 6 months prior to randomization
- Must not have any evidence of distant disease based on baseline imaging done within 28 days prior to randomization
- Must not have received anti-PD-1/PD-L1 therapy for recurrent disease (see protocol for details)
- HIV-infected patients are eligible per protocol
- Must have no known history of Hepatitis B or active Hepatitis C infection
- Must not have a current active infection that requires systemic treatment at time of randomization
- No history of non-infectious pneumonitis requiring steroids within 3 years prior to randomization
- No history of solid organ/stem cell transplant
- Must not be on immunosuppressive medication within 7 days of randomization (exceptions per protocol)
- Patients with known history/current symptoms of cardiac disease/history of treatment with cardiotoxic agents: NYHA Class III/IV heart failure is not eligible
- Must not have received a live vaccine within 30 days prior to first dose of study drug
- Must not have ≥ Grade 3 hypersensitivity to pembrolizumab and/or any of its excipients
- Must not have an active autoimmune disease that required systemic treatment in the past 2 years (see protocol for details)

Treatment Plan

See Section 5.0 for Complete Treatment Details

Arm A (re-irradiation plus pembrolizumab):

- Re-irradiation (IMRT or Proton) 2 Gy once daily x 30 fractions for a total of 60 Gy
- Pembrolizumab 400 mg IV over 30 minutes on the first day of radiation (+2), to continue q 6 weeks x 9 cycles (~12 months)

Arm B (re-irradiation plus platinum chemo):

- Re-irradiation (IMRT or Proton) 2 Gy once daily x 30 fractions for a total of 60 Gy
- Cisplatin 40 mg/m² IV (1 hour) weekly x 6 cycles OR carboplatin AUC 2 IV (1 hour) weekly x 6 cycles; see protocol for criteria of when to give carboplatin

Arm C (pembrolizumab monotherapy):

- Pembrolizumab 400 mg IV over 30 minutes q 6 weeks x 9 cycles (~12 months)

Notes:

- *A patient must be randomized within 8 weeks of surgery and treatment started within 10 weeks of surgery*
- *Pembrolizumab or doses of chemotherapy can be given before or after radiation*
- *All cycles of pembrolizumab after the first one have a +/- 3 day window*

Study Chair:
Dan P. Zandberg, MD

Study Co-chairs:
Zain Husain, MD
Mihir Patel, MD

Patient Enrollment

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

Protocol Information

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

Please Enroll Your Eligible Patients!

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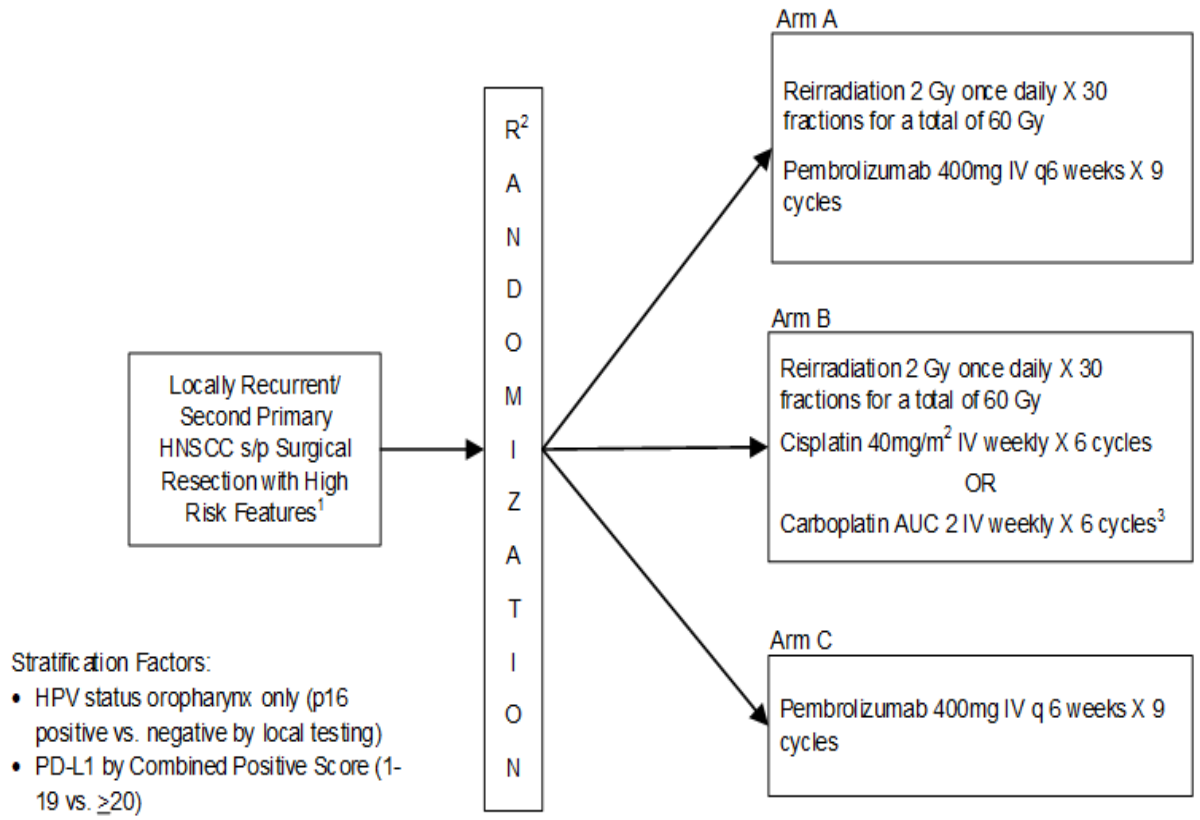
Schema



Stratification Factors:

- HPV status oropharynx only (p16 positive vs. negative by local testing)
- PD-L1 by Combined Positive Score (1-19 vs. ≥20)
- Received prior anti-PD-1/PD-L1 as part of curative intent therapy: Yes vs. No

Accrual Goal: 282

1. High risk features include Positive Margins and/or Extranodal Extension.
2. Randomization is 1:1:1 across all arms.
3. Carboplatin will be given for patients who are ineligible for cisplatin.