Version 07/21/22 (Add. #8)

NCI National Clinical Trials Network

EA6174/STAMP

For Patients with Merkel Cell Carcinoma

EA6174 Available Through ECOG-ACRIN Cancer Research Group

STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, A Phase III Trial

Patient Population

See Section 3.0 for Complete Eligibility Details

- ≥18 years of age, adequate lab values
- ECOG PS 0-2 (however, patients with a PS of 3 because they are wheel chair bound due to congenital/traumatic events more than 1 year before the diagnosis of Merkel cell carcinoma are eligible)
- Must not be pregnant or breast-feeding; contraception must be used per protocol
- Must have a histological confirmation of diagnosis of Merkel cell carcinoma (MCC), pathologic stages (AJCC v8) I-IIIb (see protocol for details)
- Patients with all macroscopic MCC (either identified by physical exam or imaging) have been completely resected by surgery within 16 weeks before randomization; must have disease-free status documented by exam and imaging within 8 weeks prior to randomization
- No history of distant metastatic disease
- Patients with initial presentation of MCC: no previous systemic/radiation therapy prior to surgery for MCC and cannot have completed adjuvant radiation therapy for MCC more than 6 weeks prior to randomization; patients actively undergoing RT/completed adjuvant RT within 6 weeks of randomization are eligible, as long as resection date is within 16 weeks of randomization
- Patients who are HIV+/have HBV or HCV are eligible per protocol
- Must not be on active immunosuppression, have a history of life threatening virus, have had other (besides non-melanoma skin cancers or recent indolent cancers) invasive cancer diagnosis in the last 2 years, or have had immunotherapy of any kind within the last 2 years prior to randomization
- No history of non-infectious pneumonitis that required steroids or has current pneumonitis
- Operative notes from patient's surgical resection must be accessible

Treatment Plan

See Section 5.0 for Complete Treatment Details

1 cycle = 21 days

Arm A:

- Pembrolizumab 200mg IV day 1, cycles 1-17 (infusion timing should be as close to 30 minutes as possible [5/+10 minutes permitted])

Arm B:

- Standard of care observation
- Patients will be followed every 3 months during the first year; thereafter, patients will continue long-term follow-up with visits required every 6 months for 5 years from study entry

See protocol for recommendations for Radiation Therapy (RT):

- Recommended for patients with high risk features
- Regimens, treatment fields, and dose constraints should follow NCCN and AAPM guidelines and/or institutional standard of care
- When determining adjuvant radiation, the primary site and the draining nodal basin should be considered separately
- Radiation is recommended to commence within 14 days of day 1 cycle 1 (both arms)
- Arm A patients can undergo sequential rather than concurrent RT, however, pembrolizumab must be initiated within 42 days of completing RT
- Either photon, proton, or electron based RT can be used; 3D-CRT and IMRT are allowed
- Total prescription dose: 50-60 Gy in 25-30 fractions to the PTVp; doses beyond this range are acceptable in standard care institutions and with approval by the study team
- *Note: Patients with prior radiation at a non-IROC provider are eligible for the trial (see protocol for details)*

Study Chair:
Brian R. Gastman, 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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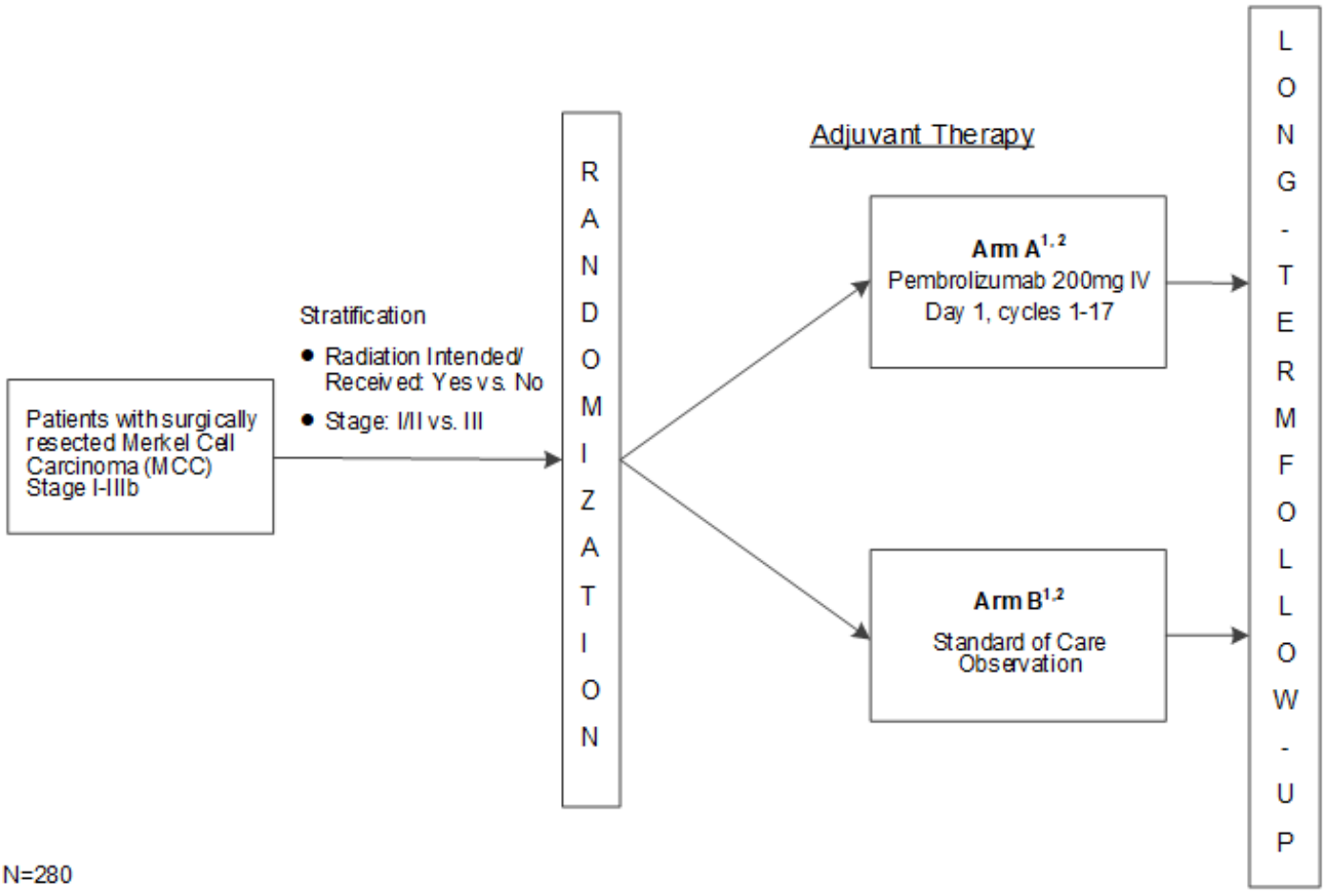
ECOG-ACRIN cancer research group

EA6174

Schema



N=280

1 cycle = 21 days (3 weeks)

1. Restaging Imaging will include CT C/A/P (and H&N if a H&N primary tumor) and/or PET/CT on a 6 month basis through 5 years from randomization.
2. If indicated: prefer optional radiation therapy to begin within 14 days of systemic therapy for concurrent therapy. Sequential radiation and systemic therapy is allowed. Patients with prior radiation at a non Radiation Oncology Core (IROC) provider are eligible for the trial. If the patient has not received radiation, and treatment at a Radiation Oncology Core (IROC) provider is not possible, the patient can start and complete radiation prior to enrolling