NCI Community Oncology Research Program

EAQ172

ECOG-ACRIN cancer research group
Reshaping the future of patient care

For Patients with Steroid-Refractory Pneumonitis

EAQ172 Available Through ECOG-ACRIN Cancer Research Group

Optimizing Immunosuppression for Steroid-Refractory Anti-PD-1/PD-L1 Pneumonitis

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years; ECOG PS 0-3; English-speaking; ability to understand and willingness to sign an informed consent (patients with a LAR/caregiver/family member available are also eligible)
- Must be willing and able to undergo arterial blood gas assessment as per the treating investigator
- Women must not be pregnant or breastfeeding
- May have any solid tumor/hematologic malignancy; may have received any number of lines of prior systemic therapy
- Must have received treatment with an anti-PD-1/PD-L1 agent either alone/in combination with another anti-cancer agent, as their most recent therapy prior to the development of pneumonitis; may have received anti-PD-1/PD-L1 therapy as standard of care/part of a clinical trial; must not be receiving anti-PD-1/PD-L1 in combination with the anti-cancer agents per protocol
- Must have steroid-refractory pneumonitis defined per protocol
- Must have had pathogen-negative infectious diagnostic evaluation within 14 days of randomization (must include items per protocol)
- Must have had pathogen-negative bronchoscopic assessment of BAL fluid within 14 days of randomization, per protocol
- No clinical evidence of cardiac dysfunction as an alternative diagnosis to steroid-refractory pneumonitis
- Must not be receiving concurrent radiation therapy to the chest
- Must not be deemed to have radiation pneumonitis (patients with a history are eligible per protocol)
- No pre-existing interstitial lung disease/pneumonitis requiring corticosteroid therapy from any other cause
- No absolute contraindication to IVIG/infliximab (see protocol); no contraindication for CT scan
- Must have negative tuberculosis assessment within 14 days of randomization (see protocol)

Treatment Plan

See Section 5.0 for Complete Treatment Details

Arm A:

- Infliximab 5 mg/kg IV on day 1 followed by a 4-6 week corticosteroid taper, starting from a dose of prednisone 1-2 mg/kg (or methlyprednisolone) either orally or IV in divided doses, as determined by the treating investigator
  - ◊ Corticosteroid taper to commence from Day 1 of the first infliximab dose
- Second dose of infliximab may be delivered 14 days after the first dose as per the treating investigator
  - ◊ If this occurs, corticosteroid taper to restart day 14
  - ◊ Infliximab may be received per locally obtainable formulation
- Patient should be under assessment for latent or active tuberculosis per institutional guidelines

Arm B:

- IVIG 2g/kg divided as per institutional guidelines as an IV infusion, followed by a 4-6 week corticosteroid taper, starting from a dose of prednisone 1-2 mg/kg (or methylprednisolone) either orally or IV in divided doses, determined by the treating investigator
  - ◊ Corticosteroid taper to commence from Day 1 of the first IVIG dose

Notes:

- *Dosing is based on actual body weight*
- *Treatment may be delivered either as outpatient or inpatient, at the discretion of the treating investigator*
- *Patients will keep a pill calendar (corticosteroids) per protocol*
- *All patients will undergo a chest CT during study screening, and days 1, 14, and 28*

Study Chair:
Jarushka Naidoo, MB, BCH

Co-Chair:
Sheetal Kircher, MD

Patient Enrollment

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

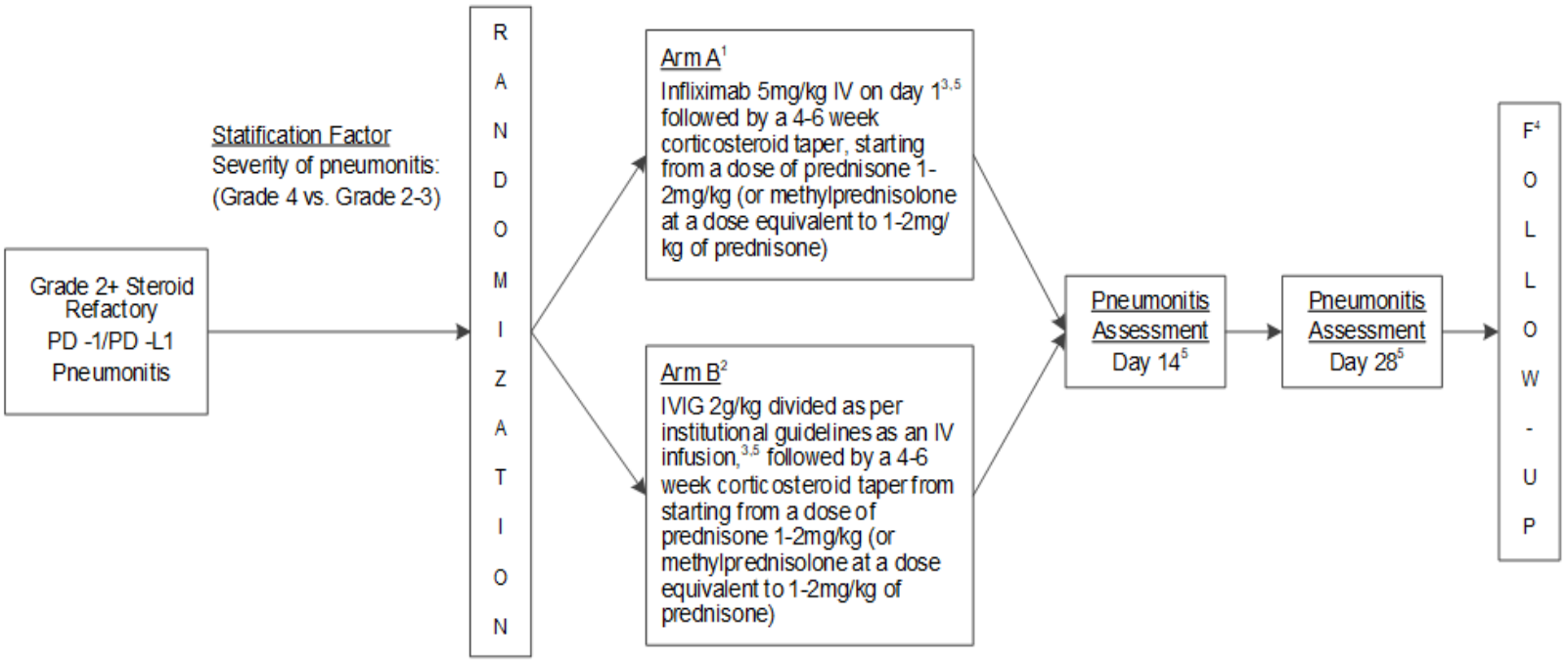
Protocol Information

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

Please Enroll Your Eligible Patients!

EAQ172

Schema



Accrual Goal = 36

1. A second dose of infliximab may be delivered 14-days after the first dose as per the treating investigator. If a second dose of infliximab is given, a prednisone taper will be restarted at Day 14.
2. IVIG may be delivered as either Privigen, Gammagard or Gamunex-C as per site standard of care.
3. Either as an inpatient or outpatient.
4. All patients will be followed up on both Days 42 and 56.
5. Required sample submission of 7 green top heparin tubes at Days 1, 14, and 28. Please see Section 7.2 for details.