

NCI

National
Clinical
Trials
Network

EA4232

ECOG-ACRIN
cancer research group**Please Enroll
Your Eligible
Patients!****For Patients with Peripheral T Cell Lymphoma****EA4232 Available Through ECOG-ACRIN Cancer Research Group**

A Randomized Phase III Study to Evaluate Benefits of Autologous Stem Cell Transplant in Patients with Peripheral T Cell Lymphoma that Achieved a First Complete Remission (CRI) Following Induction Therapy (PTCL-STAT)

Patient Population

See Section 3 for complete eligibility criteria

- Age \geq 18 and \leq 75 years, ECOG PS 0-2, adequate lab values within 14 days of randomization
- Must have histologically proven peripheral T-cell lymphoma (PTCL) in one of the following:
 - ◇ Anaplastic large cell lymphoma (ALCL) ALK-negative
 - ◇ Angioimmunoblastic T-cell lymphoma (AITL)
 - ◇ Nodal PTCL with TFH phenotype
 - ◇ Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
- Must have undergone induction treatment with an anthracycline-based chemotherapy
- Must have achieved radiologic complete remission following induction therapy as defined by the Lugano criteria with a Deauville score between 1-3 by PET-CT (note: there is no central review required; status is determined by the enrolling institution)
- Must be eligible for high dose chemotherapy and autologous stem cell transplant (ASCT) per the enrolling institutional guidelines and be ready to proceed with ASCT if randomized to that arm
- Must not have active infection requiring IV systemic antimicrobial at time of randomization
- Must not be pregnant or breastfeeding
- HIV, HBV, or HCV-infected patients are eligible per protocol

Treatment Plan

See Section 5 for complete treatment details

Arm A (Observation):

- Patients will be followed as outlined in Section 7.1 until progression
- At the time of progression, patients will receive standard of care treatment per investigator's discretion and will continue to be followed for overall survival
- Stem cell collection and banking during the observation phase is allowed

Arm B (High Dose [HD] Chemotherapy + ASCT):

- Stem cell mobilization must start within 90 calendar days after randomization
- All aspects of ASCT are performed per institutional standard of care at the transplant center
- The selection of the mobilization regimen and HD chemotherapy regimen will follow institutional practice for ASCT. Premedication, antiemetics, emergency medication, and supportive care will follow institutional practice for the specific regimen that is chosen

Note:

- *If less than 2 million CD34+ cells per kg of patient's actual body weight (or ideal body weight per institutional guidelines) are collected, the patient will be considered to have discontinued protocol therapy*
- *Dose modifications/delays of the stem cell mobilization or HD chemotherapy are permitted for Arm B*

Study Chair:

Nora Bennani, MD

SWOG Co-Chair:

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Alliance Co-Chair:

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CCTG Co-Chair:

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BMT CTN Chair:

Mehdi Hamadani, MD

BMT CTN Co-Chair:

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Patient Enrollment (Oncology Patient Enrollment Network [OPEN])

<https://open.ctsu.org/open>



1-888-823-5923

Protocol Information (ECOG-ACRIN Operations – Boston)

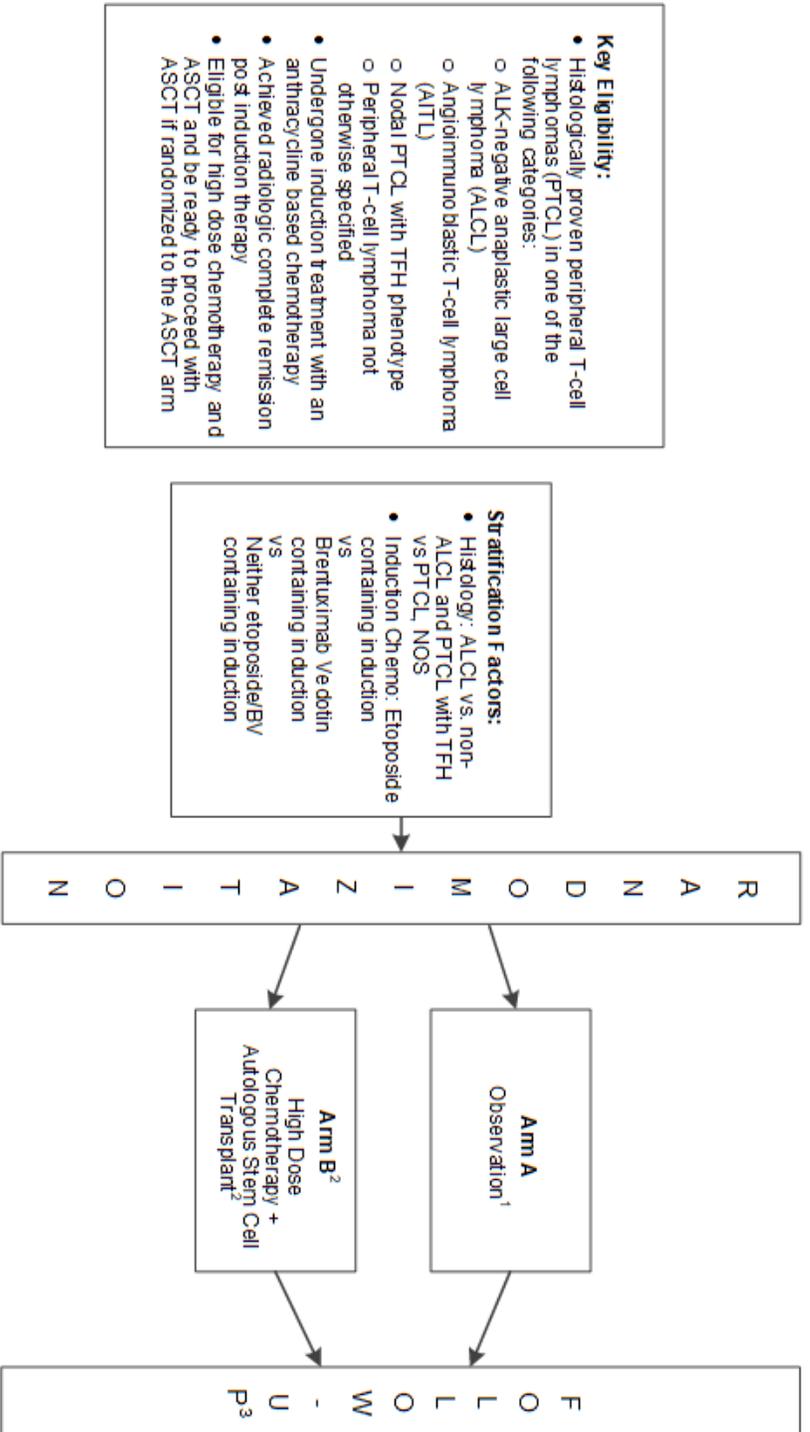
<http://ecog-acrin.org> (Member Login)



1-857-504-2900

EA4232

Schema



Accrual Goal: N = 294

Randomized 1:1

NOTE: This study utilizes new streamlined Standard Practices for protocol development and data collection designed to reduce data submission in IND-exempt trials and reduce the operational burden of participating in NCTN trials.

1. Patients randomized to Arm A Observation will be followed serially with PET-CT and CT imaging as outlined in Section 7.1. Please refer to Section 5.1.1 for additional information
2. Arm B: All aspects of the ASCT procedure, including stem cell mobilization, stem cell collection, high-dose chemotherapy, ASCT infusion, and post-transplant supportive care will be performed as per institutional guidelines. Please refer to Section 5.1.2 for additional information.
3. All patients will be followed for response until progression and for survival for 12 years from the date of randomization. Refer to Section 7 for additional information.