

An Intergroup Approach for Advanced Stage Classical Hodgkin Lymphoma (cHL) in Adolescents and Young Adults (AYA): SWOG S1826.

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Introduction

Treatment approaches to pediatric and adult cHL have varied considerably. This has resulted in gaps in understanding risk prediction and optimal therapy for de-novo advanced stage disease across the adolescent and young adult (AYA) age spectrum. In collaboration with adult research groups through the U.S. National Cancer Institute's National Clinical Trials Network (NCTN), earlier access to novel agents such as immunotherapy could be facilitated for high risk AYA. The PD-1 inhibitor Nivolumab (Nivo) has safety and efficacy in relapsed and refractory disease in children and adults, but has not been evaluated in de-novo disease to date.

Methods

Leaders in lymphoma, including all North American cooperative group chairs, Cancer Therapy Evaluation Program (CTEP) representatives and patient advocates met to establish consensus on the comparison arms and study design, based on recent historical approaches across adult and pediatric groups. Study champions were identified across all North American cooperative groups and included expertise in imaging, radiation oncology, biology and patient-reported outcomes. A therapeutic study was designed with the primary aim being to compare progression-free survival with novel targeted agents in advanced stage cHL.

Results

The trial, led by SWOG Cancer Research Network, opened to accrual in July 2019. Eligibility criteria include

patients \geq 12 years of age with Stage III or IV disease. Patients are randomized (1:1) to 6 cycles of either Nivo-Adriamycin, Vinblastine, Dacarbazine (AVD) or Brentuximab vedotin (Bv)-AVD. Enrollment is being stratified by age, baseline International Prognostic Score, and provider intent to use involved site radiation therapy (ISRT). Protocol-prescribed ISRT is response-adapted, based on end of therapy imaging. The primary endpoint is a comparison of progression-free survival between arms. Secondary clinical endpoints include comparison of: overall survival, metabolic response at the end of therapy, physician-reported adverse events, patient-reported adverse events, and health-related quality of life (overall, and specific to fatigue and neuropathy).

Conclusion

This unique intergroup collaboration demonstrates the process and the feasibility of consensus study designs toward early adoption of targeted therapies and harmonization of treatment approaches for AYA populations.