SWOG S1826：青少年和年轻成人（AYA）晚期经典型霍奇金淋巴瘤的组间协作研究

An intergroup collaboration for advanced stage classical Hodgkin lymphoma (cHL) in adolescents and young adults (AYA): SWOG S1826

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背景：儿童 cHL 的治疗与成人 cHL 的治疗差异很大。因此，在青少年和年轻成人（AYA）年龄段的新发晚期疾病的风险预测和最佳治疗方面存在差距。通过美国国家癌症研究所的国家临床试验网络（NCTN）与成人研究小组的合作，可以促进 AYA 新型药物的早期开发。PD-1 抑制剂 Nivolumab（Nivo）在儿童和成人的复发性和难治性疾病中具有安全性和有效性，但迄今为止尚未在该新型疾病中进行评估。

方法：北美合作小组淋巴瘤主席，癌症治疗评估计划（CTEP）代表和患者倡导者根据最近成人和儿科群体的历史方法，就比较组和研究设计达成共识。在北美合作组织中确定了研究组，包括在影像学、放射肿瘤学、生物学和患者报告结果等方面专业知识的学者。治疗性研究

的主要设计目的是比较晚期 cHL 中新型靶向药物的无进展生存期。由 SWOG 癌症研究网络领导的 S1826（NCT03907488）已于 2019 年 7 月开放招募。招募资格标准包括年龄> 12 岁的 III 期或 IV 期 cHL。患者被随机（1：1）分配给予 6 个周期的 Nivo-Adriamycin, Vinblastine, Dacarbazine (AVD) 或 Brentuximab vedotin (Bv)-AVD。按年龄、基线期国际预后评分和提供者使用介入放射治疗（ISRT）的意愿对患者进行分层。协议规定的 ISRT 是基于治疗结束成像的缓解调整。主要终点是两组之间无进展生存期的比较。次要临床终点包括以下方面的比较：总生存期，治疗结束时的代谢反应，医生报告的不良事件，患者报告的不良事件以及与健康相关的生活质量（总体而言，且特定于疲劳和神经病变）。这种独特的组间合作展示了共识研究设计的过程和可行性，以便尽早采用针对性治疗和协调 AYA 人群的治疗方法。临床试验信息：NCT03907488

原文摘要：

Abstract

Background: Treatment for pediatric cHL varies considerably from that in adult cHL. Hence there are gaps in risk prediction and optimal therapy for de-novo advanced stage disease across the adolescent and young adult (AYA) age spectrum. Early access to novel agents for AYA could be facilitated via collaboration with adult research groups through the U.S. National Cancer Institute’s National Clinical Trials Network (NCTN). 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: North American cooperative group lymphoma 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 North American cooperative groups and include 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. S1826 (NCT03907488), led by SWOG Cancer Research Network, opened to accrual in July 2019. Eligibility criteria include age > 12 years, and Stage III or IV cHL. Patients are randomized (1:1) to 6 cycles of either Nivo-Adriamycin, Vinblastine, Dacarbazine (AVD) or Brentuximab vedotin (Bv)-AVD. Enrollment is 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). 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. Clinical trial information: NCT03907488

参考文献：

Castellino SM, LeBlanc ML, Herrera AF, Parsons SK, Punnett A, Hodgson DC, Rutherford SC, Khan N, Constine LS and Davison K, et al: An intergroup collaboration for advanced stage classical Hodgkin lymphoma (cHL) in adolescents and young adults (AYA): SWOG S1826. J CLIN ONCOL 38: S8067, 2020.