LYMPHOMA COMMITTEE

CONTENTS

Patient Registrations to Studies

by 12 Month Intervals
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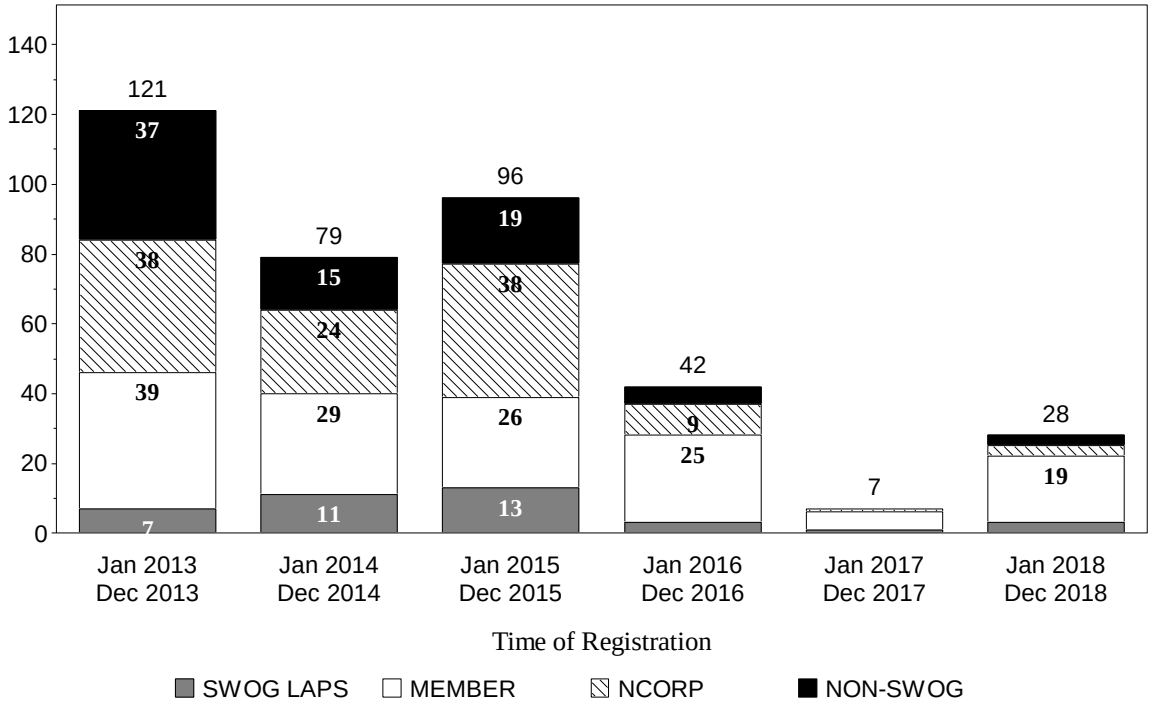

Screening registrations and registrations to Biologic only studies are excluded.

Patient Registrations by Study and Arm

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	Jul 2018 Dec 2018	Jan 2018 Jun 2018	Jul 2017 Dec 2017	All Patients
S1608 FL, TGR-1202/Lenalidomide/CHOP or Benda +Ob				
Randomization				
TGR-1202 + Obinutuzumab	1	2	0	3
Lenalidomide + Obinutuzumab	3	1	0	4
CHOP + Obinutuzumab	1	3	0	4
Bendamustine + Obinutuzumab	1	0	0	1
	6	6	0	12

Non-SWOG Studies with SWOG-Credited Registrations

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Studies with Accrual from July 2017 - December 2018

	SWOG Champion	SWOG Accrual Jul 2018 Dec 2018	SWOG Accrual Jan 2018 Jun 2018	SWOG Accrual Jul 2017 Dec 2017	SWOG Total	Total Accrued
A051301 ABC DLBCL, Auto HCT and Ibrutinib/Placebo Date Activated: 07/15/16 *Most Recent Progress Report*	P. Stiff	0	1	4	6	34
EA4151 Lymph, AHCT +/-Ritux, MRD Neg Date Activated: 08/29/17 *Most Recent Progress Report*	B. Till	9	6	0	15	61

S1204 Surveillance

A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients

Study Chairs:
S Ramsey, D Hershman

Statisticians:
J Unger, K Arnold

Data Coordinator:
M Yee

Date Activated:
08/29/2013

Date Closed:
02/15/2017

Objectives

Among newly diagnosed cancer patients presenting to SWOG-affiliated community and academic oncology clinics, estimate the prevalence of human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection.

Evaluate known sociodemographic, clinical, and behavioral factors that are significantly associated with previously undiagnosed HIV, HBV, and/or HCV infection in a population of people with newly diagnosed cancer

Among patients who are identified as having HIV, HBV, and/or HCV, describe the timing and type of treatments received (if any), both for the viral infections and the cancers.

Describe the type of adverse events possibly attributable to the patient's viral status in patients with HIV, HBV, and/or HCV infection.

Using simulation modeling that is directly informed by the data obtained from this study, determine the cost-effectiveness (expressed as cost per infection detected and cost per year of life gained) of (1) routine, universal screening and (2) risk factor-directed screening of newly diagnosed cancer patients for HIV, HBV and/or HCV versus current care.

Patient Population

Patients must be presenting for evaluation or treatment for the first diagnosis of a new solid or hematologic cancer malignancy. Confirmed diagnosis date must be within 120 days prior to first clinic visit as a newly diagnosed cancer patient at the registering clinic. Patients presenting for "second opinions" of confirmed malignancies are eligible, including those who have started cancer treatment at other facilities. Patients must be registered within 90 days after their first clinic visit. Patients must not have been diagnosed with a malignancy other than the current malignancy within the past five years, with the exception of basal cell or squamous cell skin cancer, in situ cervical cancer, or in situ breast cancer. Patients must have no evidence of disease for a prior malignancy for at least five years prior to randomization except as noted above.

Patients must be 18 years of age or older. Patients must have had their blood drawn for viral status testing for HIV, HBV and HCV or provide acceptable viral status documentation prior to registration, as defined in the protocol. Note that patients must have blood drawn for testing prior to registration for any of the three viruses not covered by the documentation. Patients are allowed to participate in other clinical trials.

Accrual Goals

A total of 3,061 patients will be accrued to achieve 3,000 eligible patients.

Summary Statement

For the current status of this study, please refer to the Cancer Care Delivery chapter.

S1608 Phase II

Coordinating Group: SWOG

Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma

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Participants:
SWOG, CTSU (Supported by Alliance, ECOG-ACRIN)

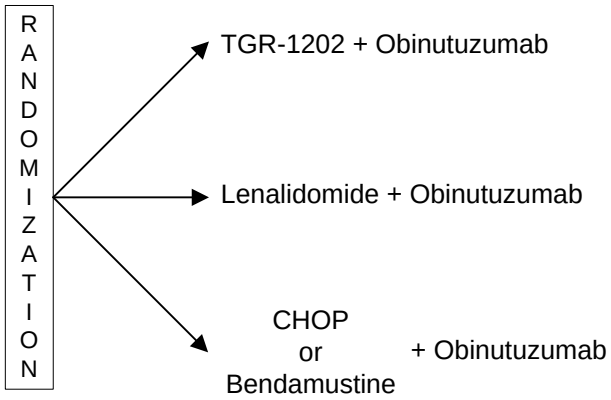
Date Activated:
08/10/2017

Study Chairs:
P Barr, B Link (Alliance), C Flowers (ECOG-ACRIN)

Statisticians:
H Li, M LeBlanc

Data Coordinator:
I Syquia

SCHEMA



Objectives

To compare the complete response rate at six cycles after randomization as defined by centrally read PET/CT (integral biomarker) of two targeted therapeutic regimens (obinutuzumab + TGR-1202 or obinutuzumab + lenalidomide) with obinutuzumab + chemotherapy (CHOP or bendamustine) in patients with early relapsing or refractory follicular lymphoma.

To validate the prognostic association of the m7-FLIPI model, demonstrating that the population of follicular lymphoma patients who respond poorly to chemoimmunotherapy are enriched for having a high-risk m7-FLIPI score, and that the score is associated with progression-free survival (integrated biomarker).

To estimate the 30 month sustained complete response rate (CR30) defined by centrally read PET/CT with each of the regimens in this early relapsing or refractory follicular lymphoma population.

To estimate best response at 12 cycles of therapy, progression-free survival, duration of response, and

overall survival with each of the combinations in early relapsing or refractory follicular lymphoma.

To evaluate the adverse effects of each of the regimens in early relapsing or refractory follicular lymphoma.

To evaluate the predictive performance of non-invasive genotyping (m7-FLIPI in circulating tumor DNA) of plasma at study entry relative to standard tumor genotyping (m7-FLIPI) of formalin-fixed paraffin-embedded tumor tissue.

To evaluate the association between the detection of active lymphoma by PET/CT and the detection of circulating tumor DNA in plasma at baseline, after 6 and 12 cycles, and at 30 months after initiation of study therapy

Patient Population

Patients must have follicular lymphoma (Grade I, II or IIIa) confirmed at initial diagnosis and at relapse with identifiable FDG avid disease on PET/CT. Patients must not have involvement with large cell lymphoma. Patients must have either failed to achieve a complete remission, or must have relapsed within two years after completing CHOP or bendamustine-containing chemoimmunotherapy. Patients must have the components of Follicular Lymphoma International Prognostic Index (FLIPI) available from diagnosis and at time of registration. Additionally, patients must have beta-2-microglobulin collected at time of registration. Patients must not have clinical evidence of central nervous system involvement by lymphoma.

Patients must have received only one course of chemotherapy, containing at least three cycles of CHOP or bendamustine. Patients may have additionally received anti-CD20 antibody therapy prior to CHOP or bendamustine therapy, or maintenance anti-CD-20 antibody based therapy or consolidative radioimmunotherapy within two years of the last dose of the CHOP or bendamustine therapy. Patients must have completed systemic therapy at least 21 days prior to registration or completed radiommunotherapy at least 84 days prior to registration. Patients must have recovered from all treatment related toxicities prior to registration. Patients must not have had prior anthracycline based therapy, or any prior treatment with any PI3K inhibitor or lenalidomide. Relapsed patients must not have received any intervening chemotherapy. Patients must be able and willing to take prophylaxis as listed in the protocol.

Patients must be at least 18 years of age and have a Zubrod performance status of 0-2. Patients must have adequate renal, hepatic, cardiac and hematologic function. Patients with Hepatitis B virus infection, or Hepatitis C virus infection, or known HIV infection are eligible with restrictions. Females of childbearing potential (FCBP) must have a negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL within 10 - 14 days prior to registration.

Stratification/Descriptive Factors

Patient randomization will be stratified according to the following factors: (1) previous receipt of maintenance therapy: yes vs no; (2) prior chemoimmunotherapy: CHOP-based vs bendamustine-based; and (3) refractory status: lack of CR after completing first course of chemoimmunotherapy vs disease relapse within two years of completing chemoimmunotherapy. If patients meet the definition of both refractory and relapsing within two years, they will be grouped with the refractory cohort.

Accrual Goals

The accrual goal for this study is 150 patients to achieve 135 eligible patients. Interim analyses are planned after response data for six cycles of treatment are available for half of patients on each arm.

Summary Statement

In order to increase opportunity for accrual, the protocol was amended to expand the eligibility criteria to include follicular lymphoma patients who relapsed within two years of completing their first course of chemotherapy (one course, containing at least three cycles of either CHOP or bendamustine-based therapy) plus anti-CD20 therapy. This protocol revision was effective on October 2, 2018.

As of December 31, 2018, 12 patients had been registered to this study and all are currently eligible.

One patient on the TGR-1202 + obinutuzumab arm discontinued treatment; the reason for treatment discontinuation is currently under review.

Among 11 patients assessed for toxicity, two experienced Grade 4 neutropenia, one patient on the CHOP + obinutuzumab arm and one patient on the TGR-1202 + obinutuzumab arm who also experienced Grade 3 rash maculo-papular. Five patients experienced Grade 3 adverse events as maximum degree, including three patients on the CHOP + obinutuzumab arm and one patient on the

lenalidomide + obinutuzumab arm with hematologic toxicities. One patient on the TGR-1202 + obinutuzumab arm experienced Grade 3 leukopenia, neutropenia, community-acquired pneumonia (coded as "Infections/infestations-Other"), lung infection, and intracranial hypertension (coded as "Vasc disorders-Other, spec").

Registration by Institution

Registrations ending December 31, 2018

Institutions	Total Reg
Rochester, Univ of	5
City of Hope Med Ctr	1
CRC West MI NCORP	1
Heartland NCORP	1
Utah, U of	1
ECOG-ACRIN	2
ALLIANCE	1
Total (7 Institutions)	**12**

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2018; Data as of February 6, 2019

	TOTAL	TGR-1202 + Obinutuzumab	Lenalidomide + Obinutuzumab	CHOP + Obinutuzumab	Bendamustine + Obinutuzumab
NUMBER REGISTERED	12	3	4	4	1
ELIGIBLE	12	3	4	4	1
Analyzable, Pend. Elig.	2	1	1	0	0
ADVERSE EVENT ASSESSMENT					
Evaluable	11	3	3	4	1
Too Early	1	0	1	0	0

Patient Characteristics

Registrations ending December 31, 2018; Data as of February 6, 2019

	TGR-1202 + Obinutuzumab (n=3)		Lenalidomide + Obinutuzumab (n=4)		CHOP + Obinutuzumab (n=4)		Bendamustine + Obinutuzumab (n=1)	
AGE								
Median	55.2		60.4		56.0		58.1	
Minimum	51.7		49.7		51.7		58.1	
Maximum	75.4		63.0		66.7		58.1	
SEX								
Males	1	33%	4	100%	2	50%	0	0%
Females	2	67%	0	0%	2	50%	1	100%
HISPANIC								
No	3	100%	4	100%	3	75%	1	100%
Unknown	0	0%	0	0%	1	25%	0	0%
RACE								
White	3	100%	4	100%	4	100%	1	100%
PRIOR MAINTENANCE THERAPY								
Yes	0	0%	1	25%	1	25%	0	0%
No	3	100%	3	75%	3	75%	1	100%
REFRACTORY STATUS								
Lack of CR	1	33%	1	25%	0	0%	0	0%
Relapse	2	67%	3	75%	4	100%	1	100%
PRIOR CHEMOIMMUNOTHERAPY								
CHOP-based	0	0%	1	25%	0	0%	1	100%
Bendamustine-based	3	100%	3	75%	4	100%	0	0%

Treatment Summary

Registrations ending December 31, 2018; Data as of February 6, 2019

	Total
NUMBER ON PROTOCOL TREATMENT	11
NUMBER OFF PROTOCOL TREATMENT	1
REASON OFF TREATMENT	
Treatment completed as planned	0
Adverse Event or side effects	0
Refusal unrelated to adverse event	0
Progression/relapse	0
Death	0
Other - not protocol specified	0
Reason under review	1
MAJOR PROTOCOL DEVIATIONS	0
LOST TO FOLLOW-UP	0
CONSENT WITHDRAWAL AFTER TREATMENT INITIATION	0

Number of Patients with a Given Type and Grade of Adverse Event

Adverse Events Unlikely or Not Related to Treatment Excluded

Registrations ending December 31, 2018; Data as of February 6, 2019

	TGR-1202 + Obinutuzumab (n=3) Grade						Lenalidomide + Obinutuzumab (n=3) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
ALT increased	2	1	0	0	0	0	3	0	0	0	0	0
Abdominal pain	3	0	0	0	0	0	2	0	1	0	0	0
Acute kidney injury	2	1	0	0	0	0	3	0	0	0	0	0
Alkaline phosphatase increased	2	1	0	0	0	0	3	0	0	0	0	0
Anemia	2	1	0	0	0	0	2	0	0	1	0	0
Anxiety	3	0	0	0	0	0	3	0	0	0	0	0
Chills	3	0	0	0	0	0	2	0	1	0	0	0
Constipation	3	0	0	0	0	0	3	0	0	0	0	0
Dehydration	3	0	0	0	0	0	3	0	0	0	0	0
Dizziness	3	0	0	0	0	0	3	0	0	0	0	0
Dyspepsia	2	0	1	0	0	0	3	0	0	0	0	0
Dysphagia	3	0	0	0	0	0	3	0	0	0	0	0
Dyspnea	3	0	0	0	0	0	3	0	0	0	0	0
Fatigue	3	0	0	0	0	0	2	1	0	0	0	0
Fever	1	2	0	0	0	0	2	1	0	0	0	0
Flushing	2	1	0	0	0	0	3	0	0	0	0	0
Headache	3	0	0	0	0	0	1	2	0	0	0	0
Hoarseness	3	0	0	0	0	0	3	0	0	0	0	0
Hyperglycemia	3	0	0	0	0	0	3	0	0	0	0	0
Hypertension	3	0	0	0	0	0	2	0	1	0	0	0

	TGR-1202 + Obinutuzumab (n=3) Grade						Lenalidomide + Obinutuzumab (n=3) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Hypokalemia	2	1	0	0	0	0	3	0	0	0	0	0
Infections/infestations-Other	2	0	0	1	0	0	3	0	0	0	0	0
Infusion related reaction	2	0	1	0	0	0	0	1	2	0	0	0
Infusion site extravasation	3	0	0	0	0	0	3	0	0	0	0	0
Injection site reaction	3	0	0	0	0	0	3	0	0	0	0	0
Localized edema	3	0	0	0	0	0	3	0	0	0	0	0
Lung infection	2	0	0	1	0	0	3	0	0	0	0	0
Lymphocyte count decreased	1	0	1	1	0	0	3	0	0	0	0	0
MS/connective tissue disorder	3	0	0	0	0	0	2	1	0	0	0	0
Malaise	3	0	0	0	0	0	2	1	0	0	0	0
Mucositis oral	3	0	0	0	0	0	3	0	0	0	0	0
Myalgia	3	0	0	0	0	0	3	0	0	0	0	0
Nausea	2	1	0	0	0	0	3	0	0	0	0	0
Neutrophil count decreased	1	0	0	1	1	0	3	0	0	0	0	0
Oral dysesthesia	2	1	0	0	0	0	3	0	0	0	0	0
Pain in extremity	3	0	0	0	0	0	3	0	0	0	0	0
Peripheral sensory neuropathy	2	1	0	0	0	0	3	0	0	0	0	0
Platelet count decreased	2	0	1	0	0	0	2	1	0	0	0	0
Rash acneiform	3	0	0	0	0	0	3	0	0	0	0	0
Rash maculo-papular	2	0	0	1	0	0	3	0	0	0	0	0
Sinus tachycardia	3	0	0	0	0	0	2	1	0	0	0	0
Upper respiratory infection	3	0	0	0	0	0	3	0	0	0	0	0
Vasc disorders-Other, spec	2	0	0	1	0	0	3	0	0	0	0	0
Vomiting	3	0	0	0	0	0	3	0	0	0	0	0
Weight loss	3	0	0	0	0	0	3	0	0	0	0	0
White blood cell decreased	1	0	0	2	0	0	3	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	1	0	0	1	1	0	0	1	1	1	0	0

	CHOP + Obinutuzumab (n=4) Grade						Bendamustine + Obinutuzumab (n=1) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
ALT increased	4	0	0	0	0	0	1	0	0	0	0	0
Abdominal pain	3	0	1	0	0	0	1	0	0	0	0	0
Acute kidney injury	4	0	0	0	0	0	1	0	0	0	0	0
Alkaline phosphatase increased	3	1	0	0	0	0	1	0	0	0	0	0
Anemia	2	0	2	0	0	0	1	0	0	0	0	0
Anxiety	3	1	0	0	0	0	1	0	0	0	0	0
Chills	4	0	0	0	0	0	1	0	0	0	0	0
Constipation	3	1	0	0	0	0	1	0	0	0	0	0
Dehydration	3	0	1	0	0	0	1	0	0	0	0	0
Dizziness	3	1	0	0	0	0	1	0	0	0	0	0
Dyspepsia	4	0	0	0	0	0	1	0	0	0	0	0
Dysphagia	3	1	0	0	0	0	1	0	0	0	0	0
Dyspnea	2	2	0	0	0	0	1	0	0	0	0	0
Fatigue	1	1	2	0	0	0	1	0	0	0	0	0
Fever	3	1	0	0	0	0	1	0	0	0	0	0
Flushing	4	0	0	0	0	0	1	0	0	0	0	0
Headache	3	0	1	0	0	0	1	0	0	0	0	0

	CHOP + Obinutuzumab (n=4) Grade						Bendamustine + Obinutuzumab (n=1) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Hoarseness	3	0	1	0	0	0	1	0	0	0	0	0
Hyperglycemia	3	1	0	0	0	0	1	0	0	0	0	0
Hypertension	3	0	1	0	0	0	1	0	0	0	0	0
Hypokalemia	4	0	0	0	0	0	1	0	0	0	0	0
Infections/infestations-Other	4	0	0	0	0	0	1	0	0	0	0	0
Infusion related reaction	3	0	1	0	0	0	1	0	0	0	0	0
Infusion site extravasation	2	0	2	0	0	0	1	0	0	0	0	0
Injection site reaction	3	0	1	0	0	0	1	0	0	0	0	0
Localized edema	3	1	0	0	0	0	1	0	0	0	0	0
Lung infection	3	0	1	0	0	0	1	0	0	0	0	0
Lymphocyte count decreased	2	0	0	2	0	0	0	0	1	0	0	0
MS/connective tissue disorder	4	0	0	0	0	0	1	0	0	0	0	0
Malaise	4	0	0	0	0	0	1	0	0	0	0	0
Mucositis oral	3	1	0	0	0	0	1	0	0	0	0	0
Myalgia	3	1	0	0	0	0	1	0	0	0	0	0
Nausea	1	1	2	0	0	0	1	0	0	0	0	0
Neutrophil count decreased	1	0	1	1	1	0	1	0	0	0	0	0
Oral dysesthesia	4	0	0	0	0	0	1	0	0	0	0	0
Pain in extremity	3	1	0	0	0	0	1	0	0	0	0	0
Peripheral sensory neuropathy	2	1	1	0	0	0	1	0	0	0	0	0
Platelet count decreased	2	2	0	0	0	0	1	0	0	0	0	0
Rash acneiform	3	1	0	0	0	0	1	0	0	0	0	0
Rash maculo-papular	4	0	0	0	0	0	1	0	0	0	0	0
Sinus tachycardia	4	0	0	0	0	0	1	0	0	0	0	0
Upper respiratory infection	3	0	1	0	0	0	1	0	0	0	0	0
Vasc disorders-Other, spec	4	0	0	0	0	0	1	0	0	0	0	0
Vomiting	2	1	1	0	0	0	1	0	0	0	0	0
Weight loss	3	1	0	0	0	0	1	0	0	0	0	0
White blood cell decreased	0	0	1	3	0	0	1	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	0	0	0	3	1	0	0	0	1	0	0	0

S1826 Phase III

Coordinating Group: SWOG

A Phase III, Randomized Study of Nivolumab (Opdivo) plus AVD or Brentuximab Vedotin (Adcetris) plus AVD in Patients (Age ≥ 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma

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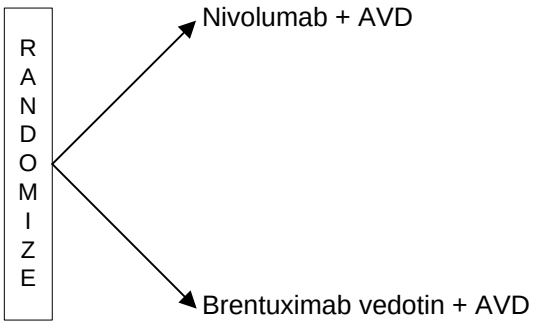
Participants:
SWOG, CTSU (Supported by Alliance, COG, ECOG-ACRIN)

Study Chairs:
A Herrera, J Friedberg, S Castellino (COG), S Rutherford (Alliance), N Khan (ECOG-ACRIN)

Statisticians:
M LeBlanc, H Li

Data Coordinator:
I Syquia

SCHEMA



Objectives

To compare the progression-free survival in patients with newly diagnosed advanced stage classical Hodgkin lymphoma randomized to N-AVD (nivolumab, doxorubicin, vinblastine, dacarbazine) versus that obtained with BV-AVD (brentuximab vedotin, doxorubicin, vinblastine, dacarbazine).

To compare overall survival in patients randomized to N-AVD versus BV-AVD.

To compare event-free survival in patients randomized to N-AVD versus BV-AVD.

To compare the metabolic complete response (CR) rate at the end of treatment in patients randomized to N-AVD versus BV-AVD.

To compare the physician-reported treatment-related adverse event rates between arms stratified by age groups.

To compare patient-reported symptoms using selected PRO-CTCAE items between arms stratified by age groups.

To compare the safety and tolerability of N-AVD versus that of BV-AVD.

To compare between arms patient-reported fatigue, neuropathy, and health-related quality of life over time (baseline, beginning of Cycle 3, 4-8 weeks after completion of treatment, and 1 and 3 years after randomization) using the PROMIS-Fatigue, the FACT/GOG-Ntx, and the PROMIS Global, respectively.

Patient Population

Patients must have histologically confirmed, newly diagnosed, previously untreated Stage III or IV classical Hodgkin lymphoma (nodular sclerosing, mixed cellularity, lymphocyte-rich, lymphocyte-depleted, or not otherwise specified). Patients must have bidimentionally measurable disease and a whole body or limited whole body PET-CT scan performed within 42 days prior to registration. Patients who have nodular lymphocyte predominant Hodgkin lymphoma or known central nervous system lymphoma are not eligible.

Patients must not have received any prior chemotherapy, radiation, or antibody-based treatment for classical Hodgkin lymphoma. Pre-treatment steroid use is permitted with restrictions as outlined in the protocol and must be discontinued prior to initiation of protocol treatment. Patients must not have had prior solid organ transplant or prior allogeneic stem cell transplantation. Patients must not have received a live vaccine within 30 days prior to planned protocol therapy.

Patients must be at least 12 years of age and have a performance status corresponding to Zubrod score of 0, 1, or 2. Patients 17 years of age or youger will be graded according to the Lansky play-performance scale. Patients must have adequate renal, hepatic, and cardiac function. HIV infected patients on effective anti-retroviral therapy with undetectable or unquantifiable viral load within six months prior to registration are eligible. Patients must not have known active Hepatitis B (HBV) or Hepatitis C (HCV) virus at time of registration. Patients must not have a history of active interstitial pneumonitis or interstitial lung disease, had a diagnosis of inherited or acquired immunodeficiency with exceptions, or have any known uncontrolled intercurrent illness. Patients must not have a condition requiring systemic treatment with either corticosteroids or other immunosuppressive medication within 14 days prior to registration or must not have active autoimmune disease that has required systemic treatment in past two years. Patients must not have Grade 2 or higher peripheral neuropathy. Patients must not have second prior malignancy except for adequately treated basal (or squamous cell) skin cancer, any in situ cancer or other cancer for which the patient have been disease free for two years. Women of childbearing potential must have a negative pregnancy test within 28 days prior to registration.

Patients who can complete Patient-Reported Outcome instruments in English, Spanish, or French must complete the required instruments prior to registration. Patients must have sufficient diagnostic tissue specimen collected prior to registration. Patients must be offered the opportunity to participate in specimen banking for future studies.

Stratification/Descriptive Factors

Patient randomization will be stratified by the following factors: (1) age (years): 12-17 vs 18-60 vs > 60; (2) International Prognostic Score: 0-3 vs 4-7; and (3) pre-specified plan to use Residual PET Radiation Therapy (Residual PET RT): yes vs no. All participating COG institutions that have pediatric patients enrolled must have declared intent for use of Residual PET RT.

Accrual Goals

The accrual goal for this study is 987 patients to achieve 940 eligible patients. Three interim analyses are planned for when approximately 25%, 50%, and 75% of expected events in the pooled arms have been observed.