SOUTHWEST ONCOLOGY GROUP
PROTOCOL FAST FACT SHEET

THIS FORM HAS BEEN DESIGNED AS A RESOURCE ONLY AND IS NOT INTENDED FOR USE IN THE FULFILLMENT OF PATIENT REGISTRATION AND TREATMENT REQUIREMENTS

S0410

TANDEM AUTOLOGOUS STEM CELL TRANSPLANTATION FOR PATIENTS WITH PRIMARY PROGRESSIVCE OR POOR RISK RECURRENT HODGKIN'S DISEASE (A BMT STUDY).

Treatment initiation Within 5 working days of registration
Drugs Provided: None

TREATMENT:
Collection of PBSC ≤ 6 weeks after completion of the last cycle of salvage chemotherapy
↓
Involved Field Radiation for Residual Tumor > 5 cm after salvage chemotherapy
↓
Cycle 1 High-Dose Therapy

Drugs	Dose	Route	Timing
Melphalan	150 mg/m^2	IV	D -1
PBSC Reinfusion	50% of collected PBSC	IV	D 0

↓
Transplant Center shall choose a single regimen for all patients treated on this protocol who are under the age of 61 (TBI/VP16/CTX or BCV).

Cycle 2 High-Dose Therapy (4-8 weeks after cycle 1)

Drugs	Dose	Route	Timing
TBI	150 cGy x 2 daily		D -8 to -5
VP-16	60 mg/kg	IV	D -4
Cyclophosphamide	100 mg/kg	IV	D -2
PBSC Reinfusion	50% of collected PBSC	IV	D 0

OR

Cycle 2 High-Dose Therapy (4-8 weeks after cycle 1)

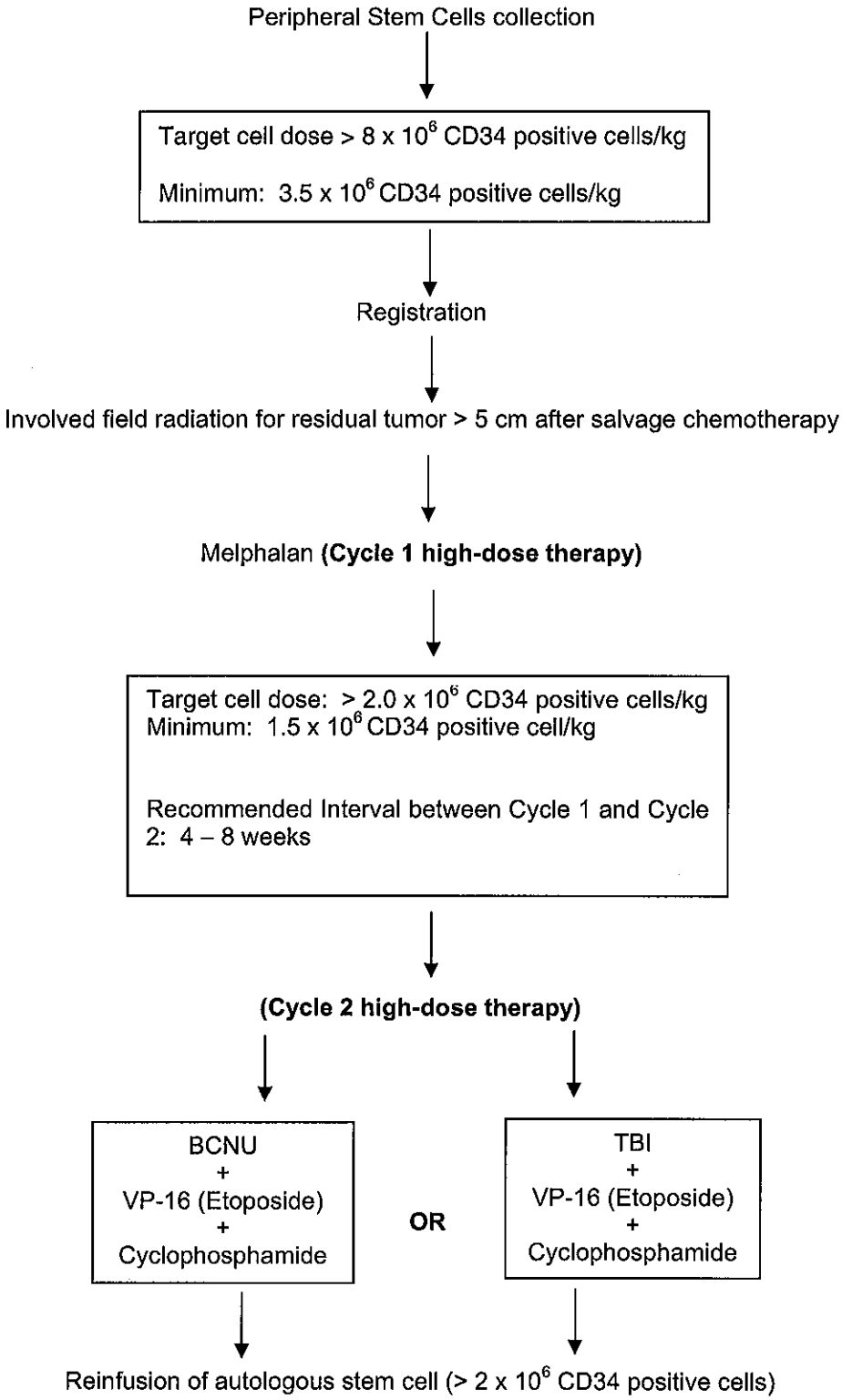
Drugs	Dose	Route	Timing
BCNU	150 mg/m^2	IV	D -6, -5, -4
VP-16	60 mg/kg	IV	D -4
Cyclophosphamide	100 mg/kg	IV	D -2
Hydration		IV	D -2, -1
PBSC Reinfusion	50% of collected PBSC	IV	D 0

Eligibility	Ineligibility
Histology or cytologically confirmed relapsed or refractory Hodgkin's disease	Clonal abnormalities detected in the pre-stem cell collection of marrow
Bilateral or unilateral bone marrow aspirate and biopsy	Prior malignancy except for adequately treated basal cell or squamous cell skin cancer, or any other cancer which the patient has been disease free for 5 yrs. Prior history of lymphoma, myelodysplastic syndrome, or leukemia (even if disease free for five years).
Minimum of 3.5 x 10^6 CD34 positive cells/kg collected according to Section 7.4.	Active bacterial, fungal or viral infection
Patients with bulk disease > 5 cm must have received IFRT prior to registration.	Pregnant or nursing female
Must have adequate sections of original diagnostic specimen available for submission	Requires therapy for coronary artery disease, cardiomyopathy, congestive heart failure or arrhythmias
≥ 15 and < 71 years of age	
PS 0 – 2	ANC < 1,500/mcL
Ejection fraction ≥ 45% by MUGA scan or 2-d ECHO with no significant abnormalities if questionable cardiac history	Patients with known HIV or AIDS Not in good medical condition that will permit aggressive HDT.
Adequate pulmonary function measured by a corrected DLCO ≥ 60% or FEV_1 ≥ 60% of predicted	Clinical or laboratory evidence of CNS involvement by Hodgkin's disease

PRESTUDY REQUIREMENTS:
≤ 28 days before registration: H&P/WT/PS; CBC/diff/platelets; bilirubin; alk phos; creatinine/creatinine clearance; EKG; chest x-ray; CT scan chest, abdomen, & pelvis (if negative, studies may have been performed within 42 days)
≤ 28 days prior to initiation of stem cell mobilization: Pulmonary function tests; MUGA or 2-D Echo
≤ 42 days before stem cell collection: Bilateral or unilateral bone marrow A&B

*This form has been developed with the support of the SWOG Nurse Oncologists' Committee.

SCHEMA


Peripheral Stem Cells collection
Target cell dose > 8 x 10^6 CD34 positive cells/kg
Minimum: 3.5 x 10^6 CD34 positive cells/kg
Registration
Involved field radiation for residual tumor > 5 cm after salvage chemotherapy
Melphalan (Cycle 1 high-dose therapy)
Target cell dose: > 2.0 x 10^6 CD34 positive cells/kg
Minimum: 1.5 x 10^6 CD34 positive cell/kg
Recommended Interval between Cycle 1 and Cycle 2: 4 – 8 weeks
(Cycle 2 high-dose therapy)
BCNU + VP-16 (Etoposide) + Cyclophosphamide
OR
TBI + VP-16 (Etoposide) + Cyclophosphamide
Reinfusion of autologous stem cell (> 2 x 10^6 CD34 positive cells)