

## 1      **PROTOCOL SYNOPSIS**

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Title	A randomized trial of BEAM plus PBSCT versus single agent high-dose therapy followed by BEAM plus PBSCT in patients with relapsed Hodgkin's disease
Indication	Early or late first relapsed Hodgkin's disease, second relapse (no prior HDCT)
Objective	To compare efficacy and toxicity of a sequential HDCT and a standard HDCT in patients with histologically confirmed relapsed Hodgkin's disease. Primary endpoint of the study is freedom from treatment failure (FFTF) in both treatment arms. Secondary endpoints are complete remission (CR), complete remission unconfirmed (CRu) rates 3 months after end of protocol, relapse-free survival (RFS), overall survival (OS), frequency of severe toxicities (WHO grade 3 or 4), and secondary neoplasia.
Study Design	A prospective, randomized, multicenter phase-III study
Sample Size	220 evaluable patients
Inclusion criteria	Patients with histologically confirmed early (CR lasting 3 to 12 months) or late (CR lasting > 12 months) relapsed HD after COPP/ABVD, COPP/ABV/IMEP, MOPP/ABV, ABVD, BEACOPP baseline or BEACOPP escalated or other multidrug chemotherapy; Patients with second relapse (any salvage therapy, no prior HDCT); age: 18 to 60 years; ECOG $\leq$ 2, no major organ dysfunction, written informed consent.
Study Procedures	After registration, patients will receive 2 cycles of DHAP plus G-CSF. After the first (and/or second) course of DHAP, PBSC will be collected by apheresis. Response evaluation will then be performed and patients with CR or PR or NC will proceed as intended via randomization. Patients will be randomized between BEAM (carmustin, etoposide, cytarabine, melphalan) followed by peripheral blood stem cell transplantation (PBSCT; arm A of the study) or high-dose (HiD) cyclophosphamide (CTX), followed by HD-methotrexate (MTX) plus vincristin, followed by HD-etoposide (VP-16), and BEAM plus PBSCT (arm B of the study).