



BMT CTN PROTOCOL #0803/AMC-071

High Dose Chemotherapy with Autologous Stem Cell Rescue for Aggressive B Cell Lymphoma and Hodgkin Lymphoma in HIV-infected Patients

Deletions to the protocol are indicated in strike-out text. Additions are noted in underlined text.

Major Changes to the Protocol

- The HIV reservoir ancillary study has been removed from the protocol. The following sections have been updated to reflect this change:
 - ~~§1.4.1 HIV Reservoirs Single Copy PCR: Therapies that impact on the latently infected reservoir might be expected to change the viremia if it mainly reflected the decay of latently infected cells. Myeloablative chemotherapy may kill cells that constitute the latency reservoir and thus might thus be expected to impact on the reservoir and the very low level viremia that can be assessed by this assay.~~
 - ~~§3.3.12 HIV and HIV Reservoir Single Copy PCR: Transplant centers will need to perform CD4 lymphocyte counts within 3 months prior to initiation of conditioning. For those patients that have (1) a CD4 count of >300/uL within 3 months prior to initiation of conditioning and (2) undetectable HIV-1 RNA in their baseline sample using the standard clinical test, additional blood samples will be collected for HIV Reservoir Cellular Studies. Samples will be collected within 1-3 weeks prior to start of conditioning, and on Day 180 and Day 365 post transplant and sent directly to a project laboratory for analysis.~~
 - ~~§4.2.1.2 Post-HCT Evaluation #10: For those patients that have (1) a CD4 count of >300/uL within 3 months of initiation of conditioning and (2) undetectable HIV-1 RNA in their baseline sample using the standard clinical test, additional blood samples will be collected for HIV Reservoir Cellular Studies. Samples will be collected on Day 180 and 1 year post transplant (See Appendix C).~~
 - ~~Tables 4.2.1.2a and 4.2.1.2b: Removed HIV Cellular Reservoir Studies from the tables.~~
 - ~~§5.5.2 Analysis of Secondary Endpoints: HIV RNA assay prior to transplant and at Day 100, 180 and 1 year post transplant (for HIV load) and quantitative measurement of HIV in quiescent CD4 cells at pre-transplant, 6 months and 12 months (HIV reservoir) will be performed. For patients with no detectable viral RNA using the standard clinical test, a single copy assay will be used to measure the viral reservoir. We will summarize this assessment of the viral copy number using descriptive statistics at each time point, and~~

we will investigate changes in the viral copy number from pre-transplant to post-transplant time points using Friedman's nonparametric test.

- The appropriate sections of Appendix C were removed to reflect the removal of the HIV reservoir ancillary study.