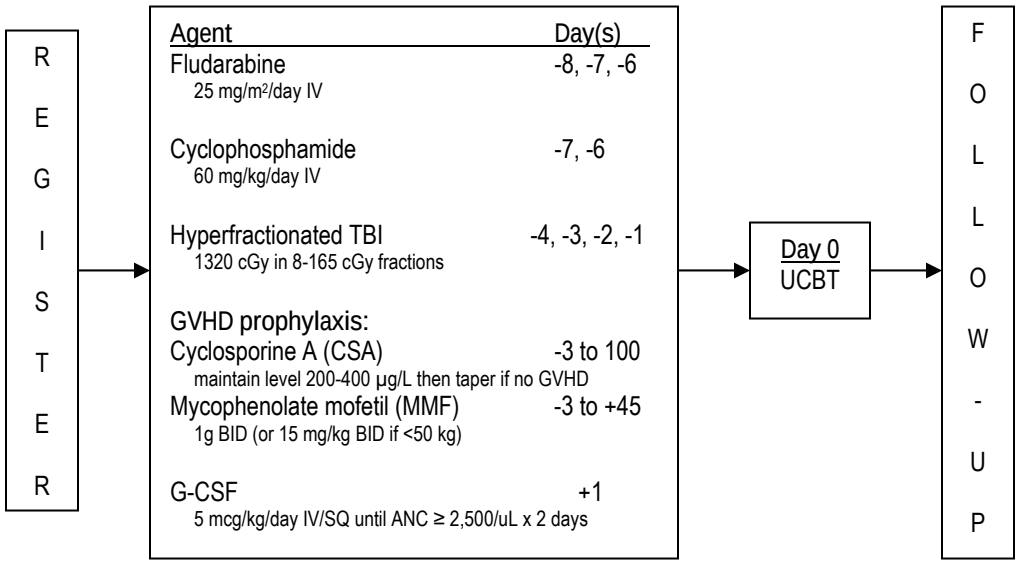
HO08402: A Phase II Multicenter Trial of Myeloablative Double Unit Umbilical Cord Blood Transplantation (UCBT) in Adults with Hematologic Malignancy



MAJOR ELIGIBILITY CRITERIA:

- Must be age 22-50 years.
- Must have one of the following hematological malignancies:
  - AML
    - CR1 at high risk for relapse as defined by: known prior diagnosis of MDS; or therapy-related AML; or WBC > 100,000; or presence of extramedullary leukemia at diagnosis; or unfavorable FAB type (M0, M5-M7); or high-risk cytogenetics
    - CR2
  - ALL
    - CR1 at high risk for relapse as defined by: WBC > 50,000; or presence of high-risk cytogenetic abnormality such as t(9;22), t(1;19), t(4;11) or other MLL rearrangements (11q23), t(8;14); or failure to achieve complete morphologic remission after 4 weeks of induction therapy
    - CR2
  - AUL or biphenotypic leukemia in CR1 or CR2
  - MDS with one of the following:
    - Low and Intermediate-1 IPSS score with either life-threatening neutropenia or thrombocytopenia, or with platelet transfusion dependence
    - Intermediate-2 or High IPSS score
- Must have Karnofsky score ≥ 70%, creatinine clearance ≥ 60 mL/min OR creatinine ≥ 1.5 mg/dL (history of renal dysfunction must have a *measured* creatinine clearance ≥ 60 mL/min), total bilirubin < 2.5 mg/dL (unless benign congenital hyperbilirubinemia), ALT/AST < 3 x ULN, albumin ≥ 2.5 g/dL, pulmonary function ≥ 60% normal, left ventricular ejection fraction ≥ 50%.
- Double Unit UCB Grafts: patient must undergo a UCB search at both NMDP banks and NYBC at a minimum; each unit must have a cryopreserved dose of at least $1.5x10^7$ TNC/kg (if unit contains red cells, the cryopreserved dose must be at least $2.0x10^7$ TNC/kg); each unit must be at least 4/6 HLA-A and B antigen and DRB1 allele matched with the recipient; each unit must be at least 3/6 HLA-A, B DRB1 antigen matched to each other; above the cell threshold of $1.5x10^7$ TNC/kg, HLA-match will take priority in unit selection.
- Must not have a suitable related donor.
- Must not have AML, ALL, AUL, biphenotypic leukemia beyond CR2, or AML evolved from myelofibrosis.
- Must not have any acute leukemia with morphologic relapse or persistent disease in BM, active extramedullary leukemia including active CNS leukemia, or require > 2 cycles of chemotherapy to obtain present remission status.
- Must not have BM aplasia, MDS with ≥ 10% BM blasts at pre-transplant workup, prior autologous or allogeneic HSC transplant at any time, prior radiation therapy rendering patient ineligible for TBI, uncontrolled infection, or seropositive or NAT positive for HIV or HTLV1.
- Women of childbearing potential must not be pregnant or breast feeding.

PRE-STUDY LABS AND TESTS:

≤ 30 days prior to conditioning regimen: CBC with differential, comprehensive metabolic panel (including albumin, LDH, serum uric acid, PT/PTT), creatinine (if creatinine ≥ 1.5 mg/dL must have a *measured* creatinine clearance), BM aspirate, trephine core if clinically indicated for morphology, surface markers, cytogenetics, FISH and molecular studies, spinal or intra-Ommaya tap (in patients with acute leukemia at risk for CNS disease), urinalysis, RBC type and screen, full dental exam, ECG, echocardiogram, MUGA scan, or cardiac MRI with measurement of left ventricular ejection fraction, chest x-ray, radiographic studies, chest CT scan, pulmonary function test, infectious disease markers (including at minimum CMV titer, Hepatitis panel [HepB sAb, HepB sAg, HepB cAb, HepC Ab], HIV 1/2 [serology *and* HIV-1 NAT or p24 antigen], HTLV-1/2, HSV, toxoplasmosis, and RPR serology testing), peripheral blood to submit to DMP laboratory, and pregnancy test (if applicable).

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