Hematopoietic Stem Cell Transplantation in the Treatment of Infant Leukemia

Status: Recruiting

Eligibility Criteria

Sex: All
Age: up to 3 Years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• Matched sibling donor (HLA 8/8), if available, or a unrelated partially HLA matched single unit based on the following priority:
  • 1st priority: 4/6 matched unit, cell dose >5 x 10^7 nucleated cells/kg
  • 2nd priority: 5/6 matched unit, cell dose > 4 x 10^7 nucleated cells/kg
  • 3rd priority: 6/6 matched unit, cell dose 3 x 10^7 nucleated cells/kg

• Patients aged ≤ 3 years at diagnosis (not age of transplant) with hematological malignancy as detailed below:
  • Acute myeloid leukemia: high risk CR1 as evidenced by:
    • High-risk cytogenetics (t(4;11) or other MLL rearrangements; chromosome 5, 7, or 19 abnormalities; complex karyotype (>5 distinct changes); 8% V2 cycles to obtain complete response (CR); CR2 or higher; Preceding myelodysplastic syndrome (MDS); All patients must be in CR or early relapse (i.e., <15% blasts in BM).
    • Acute lymphocytic leukemia: high risk CR1 as evidenced by: High-risk cytogenetic (t(4;11) or other MLL rearrangements; hypodiploid; t(9;22)); >1 cycle to obtain CR; CR2 or higher; All patients must be in CR as defined by hematological recovery, AND <5% blasts by light microscopy within the bone marrow with a cellularity of ≤40%.
    • Myelodysplasia (MDS) IPSS Int-2 or High risk (i.e. RAEB, RAEBt) or refractory anemia with severe pancytopenia or high risk cytogenetics. Blasts must be < 10% by a representative bone marrow aspirate morphology.
    • Persistent or rising minimal residual disease (MRD) after standard chemotherapy regimens: Patients with evidence of minimal residual disease at the completion of therapy or evidence of rising MRD while on therapy, MRD will be defined by either flow cytometry (>0.1% residual cells in the blast gate with immune phenotype of original leukemic clone), by molecular techniques (PCR or FISH) or conventional cytogenetics (g-banding).
    • New Leukemia Subtypes: A major effort in the field of pediatric hematology is to identify patients who are of high risk for treatment failure so that patients can be appropriately stratified to either more (or less) intensive therapy. This effort is continually ongoing and retrospective studies identify new disease features or characteristics that are associated with treatment outcomes. Therefore, if new high risk features are identified after the writing of this protocol, patients can be enrolled with the approval of two members of the study committee.

• Recipients must have a Lansky score ≥ 50% and have acceptable organ function defined as:
  • Renal: glomerular filtration rate > 60ml/min/1.73m^2
  • Hepatic: bilirubin, AST/ALT, ALP < 5 x upper limit of normal,
  • Pulmonary function: oxygen saturation >92%
  • Cardiac: left ventricular ejection fraction > 45%.

• Voluntary written informed consent before performance of any study-related procedure not part of normal medical care.

Exclusion Criteria:

• Active infection at time of transplantation (including active infection with Aspergillus or other mold within 30 days).
• History of HIV infection or known positive serology
• Myeloablative transplant within the last 6 months.
• Evidence of active extramedullary disease (including central nervous system leukemia).

Conditions & Interventions

Interventions:


Conditions:

Leukemia, Myelodysplastic Syndromes, Childhood Acute Myeloid Leukemia in Remission, Recurrent Childhood Acute Myeloid Leukemia, Secondary Acute Myeloid Leukemia, Childhood Acute Lymphoblastic Leukemia in Remission, Previously Treated Myelodysplastic Syndrome, Secondary Myelodysplastic Syndrome, Refractory Anemia With Excess Blasts in Transformation, Refractory Anemia With Excess Blasts, Refractory Anemia, De Novo Myelodysplastic Syndrome, Childhood Myelodysplastic Syndrome

Keywords:
MDS, AML

More Information

Description: To determine the incidence of engraftment (defined as achieving donor derived neutrophil count >500/uL by day 42) in young children with leukemia or myelodysplastic syndrome undergoing a partially matched single umbilical cord blood transplant (UCBT) after a myeloablative preparative regimen consisting of busulfan, melphalan and fludarabine.

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IRB Number: 0511M77206
System ID: NCT00357565

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