

Haploidentical Stem Cell Transplantation for Patients without a Matched Sibling or Unrelated Donor

A Phase II Clinical Trial: Two-arm Clinical Trial for Patients with Hematologic Malignancies and Mismatched Donors – Haploidentical and 1 Antigen Mismatched Related or Unrelated - Using a T-cell Replete Allograft and High-dose Post-transplant Cyclophosphamide

Objective:

- To determine the safety and 100-day non-relapse mortality of T-cell replete allogeneic stem cell transplantation using 3 drugs as conditioning followed by high-dose post –transplant cyclophosphamide

Eligibility Criteria:

- Patients with high risk hematologic malignancies requiring a stem cell transplant without a matched donor
- Up to 60 years old
- ECOG performance status 0-1
- Adequate organ function

Benefits for Patients:

- May produce prolonged disease-free survival in patients with hematologic malignancies
- Provides an opportunity for allogeneic hematopoietic stem-cell transplantation for patients who lack a matched related or unrelated donor



Procedures:

- Two-arm clinical trial for patient with hematologic malignancies and mismatched donors
- Arm 1: Haploidentical and Arm 2: One antigen mismatch related or unrelated
- Treatment plan is the same for both arms; uses a T-cell replete allograft and high-dose post-transplant cyclophosphamide followed by tacrolimus and mycophenolate
- Conditioning regimen includes Fludarabine 160 mg/m², Melphalan 140mg/m² and Thiotepa 10mg/kg; Infusion of bone marrow stem cells on day 0
- Two doses of cyclophosphamide are administered on day +3 and +4 post transplant for GVHD prevention
- Patients will be admitted for approximately one month and are required to be in Houston for approximately 3 months after transplant

Protocol # 2009-0266

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Schedule an appointment or make referral online at [https:// my.mdanderson.org](https://my.mdanderson.org) or call 713-563-2000. For more information about the study, contact Dr. Ciurea at 713-745-0146 or sciurea@mdanderson.org

For information on related articles or references for this study, visit <http://physicianrelations.org> or <http://clinicaltrials.gov/ct2/show/NCT01010217>

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