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Trial record **5 of 79** for: Acute Lymphoblastic Leukemia and umbilical cord
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Donor Umbilical Cord Blood Stem Cell Transplant in Treating Patients With Hematologic Malignancies

This study is ongoing, but not recruiting participants.

Sponsor:
Case Comprehensive Cancer Center

Information provided by (Responsible Party):
Case Comprehensive Cancer Center

ClinicalTrials.gov Identifier:
NCT01093586

First received: March 24, 2010
Last updated: February 28, 2013
Last verified: February 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	March 24, 2010
Last Updated Date	February 28, 2013
Start Date ICMJE	March 2009
Estimated Primary Completion Date	December 2013 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: March 25, 2010)**	Overall survival [Time Frame: On day +180] [Designated as safety issue: No]
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT01093586 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: March 25, 2010)**	• Hematologic engraftment [Time Frame: On day +42] [Designated as safety issue: No] • Disease-free and overall survival [Time Frame: At 1 and 2 years] [Designated as safety issue: No] • Duration of response [Time Frame: one and two years] [Designated as safety issue: No] • Transplant related mortality [Time Frame: On day 100 and 180] [Designated as safety issue: Yes] • Recurrence or relapse [Time Frame: one and two years in patients post UCBT] [Designated as safety issue: No] • Occurrence of serious infections [Time Frame: 1 year] [Designated as safety issue: No] • Immune reconstitution [Time Frame: Periodically for 2 years] [Designated as safety issue: No] • Toxicity related to UCB transplantation and cytoreduction as assessed by CTC v3.0 [Time Frame: three consecutive measurements on different days by day +42] [Designated as safety issue: Yes] • Incidence of acute graft-versus-host disease (GVHD) [Time Frame: At 100 days] [Designated as safety issue: No] • Incidence of chronic GVHD [Time Frame: At 1 year] [Designated as safety issue: No]
Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome Measures ICMJE	*Not Provided*

Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Donor **Umbilical Cord** Blood Stem Cell Transplant in Treating Patients With Hematologic Malignancies
Official Title ICMJE	**Umbilical Cord** Blood (UCB) Allogeneic Stem Cell Transplant for Hematologic Malignancies
Brief Summary	RATIONALE: Giving chemotherapy before a donor **umbilical cord** blood transplant (UCBT) helps stop the growth of cancer and abnormal cells and helps stop the patient's immune system from rejecting the donor's stem cells. When the stem cells from an unrelated donor, that do not exactly match the patient's blood, are infused into the patient they may help the patient's bone marrow make stem cells, red blood cells, white blood cells, and platelets. Sometimes the transplanted cells from a donor can make an immune response against the body's normal cells. Giving antithymocyte globulin before transplant and cyclosporine and mycophenolate mofetil after transplant may stop this from happening. PURPOSE: This phase II trial is studying how well donor **umbilical cord** blood stem cell transplant works in treating patients with hematologic malignancies.
Detailed Description	PRIMARY OBJECTIVES: 1. To establish the day +180 overall survival after a myeloablative unrelated double unit UCBT in a single institution setting. SECONDARY OBJECTIVES: 1. To determine the rates of hematologic and immune reconstitution in patients with high risk hematologic malignancies, who are undergoing myeloablative chemotherapy followed by infusion of double unit UCBT. 2. To determine the contribution of each umbilical cord unit to immune reconstitution with a focus on both initial (day +21 BM, and +28 PB) and sustained engraftment (day +100 BM; PB at +14, +21, +28, +35, +42, +60, +100, +180, +1 and 2 years). 3. To determine the probability of overall survival and disease free survival at one and two years. 4. To describe the incidence of disease recurrence at one and two years in patients post UCBT. 5. To describe the incidence of acute GVHD and chronic GVHD at 100 days and at one year, respectively. 6. To determine the incidence of day 100 and 180 treatment related mortality. 7. To determine the incidence of serious infectious complications in the first year after transplant. 8. To determine the incidence of donor-derived neutrophil and platelet recovery. 9. To determine the incidence of secondary lymphoproliferative diseases following transplantation with umbilical cord blood. OUTLINE: PREPARATIVE REGIMEN: Patients receive oral busulfan every 6 hours on days -8 to -5, cyclophosphamide IV on days -4 to -3, and anti-thymocyte globulin or methylprednisolone IV on days -3 to -1. TRANSPLANTATION: Patients undergo double-unit umbilical cord blood allogeneic stem cell transplantation on day 0. GRAFT-VS-HOST DISEASE PROPHYLAXIS: Beginning on day -2, patients receive cyclosporine IV and taper beginning on day 100. Patients also receive mycophenolate mofetil IV or orally every 8 hours on days -3 to 45. After completion of study treatment, patients are followed periodically.
Study Type ICMJE	Interventional
Study Phase	Phase 2
Study Design ICMJE	Endpoint Classification: Safety/Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
Condition ICMJE	• **Acute** Myeloid **Leukemia** With Multilineage Dysplasia Following Myelodysplastic Syndrome • Adult **Acute Lymphoblastic Leukemia** in Remission

	• Adult **Acute** Mega