

Trial record **7 of 50** for: hodgkin disease and umbilical cord blood[Previous Study](#) | [Return to List](#) | [Next Study](#)**Hematopoietic Stem Cell Transplantation (HSCT) Using CD34 Selected Mismatched Related Donor and One Umbilical Cord Unit (Haplo/Cord)****This study is currently recruiting participants.***Verified January 2010 by Medical College of Wisconsin***Sponsor:**

Medical College of Wisconsin

**Information provided by:**

Medical College of Wisconsin

**ClinicalTrials.gov Identifier:**

NCT01050946

First received: January 14, 2010

Last updated: January 15, 2010

Last verified: January 2010

[History of Changes](#)[Full Text View](#)[Tabular View](#)[No Study Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)**► Purpose**

This study is a means of providing transplantation to those patients who would be a stem cell transplant candidate who do not have an appropriate donor.

The use of CD34 selected haploidentical donor with an **umbilical cord** unit may help provide earlier engraftment without the need for long term immunosuppression.

This study tests a new method of bone marrow transplantation called combined haploidentical-**cord blood** transplantation. In this procedure, some of the **blood** forming cells (the stem cells) from a partially human leukocyte antigen (HLA) matched (haploidentical) related donor are collected from the **blood**, as well as cells from an **umbilical cord** are transplanted into the patient (the recipient) after administration of a "conditioning regimen". A conditioning regimen consists of chemotherapy and sometimes radiation to the entire body (total body irradiation, or TBI), which is meant to destroy the cancer cells and suppress the recipient's immune system to allow the transplanted cells to take (grow).

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Leukemia, Lymphocytic, Acute Leukemia, Lymphocytic, Chronic Leukemia, Myelocytic, Acute Leukemia, Myeloid, Chronic Lymphoma, Non-Hodgkin <b>Lymphoma, Hodgkins</b>	Other: Haploidentical/ <b>cord</b> transplant	Phase 2

Study Type: Interventional

Study Design: Allocation: Non-Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Single Group Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Phase II Study: HSCT Using CD34 Selected Mismatched Related Donor and One **Umbilical Cord** Unit**Resource links provided by NLM:**[Genetics Home Reference](#) related topics: [familial acute myeloid leukemia with mutated CEBPA](#)[MedlinePlus](#) related topics: [Cancer](#) [Hodgkin Disease](#) [Leukemia](#) [Lymphoma](#)[U.S. FDA Resources](#)

**Further study details as provided by Medical College of Wisconsin:**

## Primary Outcome Measures:

- The primary objective is to estimate the overall survival, separately in the two risk strata. [ Time Frame: 3 years ]  
[ Designated as safety issue: No ]

## Secondary Outcome Measures:

- Time to Relapse: To assess the incidence of acute leukemia or lymphoma relapse from day of transplant [ Time Frame: 2 years ]  
[ Designated as safety issue: No ]
- Time to Neutrophil Engraftment: To assess the incidence of neutrophil engraftment from day of transplant [ Time Frame: 100 days ]  
[ Designated as safety issue: No ]
- Time to Platelet Engraftment: To assess the incidence of platelet engraftment from day of transplant, [ Time Frame: 100 days ]  
[ Designated as safety issue: No ]
- Time to Acute GVHD: We will assess the incidence and severity of grades II-IV and grades III-IV acute GVHD from day of transplant.  
[ Time Frame: 100 days ] [ Designated as safety issue: No ]
- Transplant Related Mortality (TRM): TRM is death occurring in patients in continuous complete remission. [ Time Frame: 1 year ]  
[ Designated as safety issue: Yes ]
- Disease-free Survival:**Death or relapse will be considered events for this endpoint. [ Time Frame: 3 years ] [ Designated as safety issue: No ]

Estimated Enrollment: 80  
 Study Start Date: July 2009  
 Estimated Study Completion Date: July 2019  
 Estimated Primary Completion Date: July 2019 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
Haploidentical/ <b>cord</b> transplant Haploidentical/ <b>cord</b> transplant with the precondition regimen at discretion of treating physician.	Other: Haploidentical/ <b>cord</b> transplant Myeloablative preparative regimen of chemotherapy and radiation followed by mismatch related(haploidentical)donor and one unit <b>umbilical cord blood</b> transplantation. Conditioning Regimens Choice of regimen at the discretion of the treating physician <ol style="list-style-type: none"> <li>Fludarabine 30mg/m2(Days-7,-6,-5,-4,-3)-,Melphalan 70mg/m2(Day -3,-2), ATG 1.5mg/m2(Day-7,-5,-3,-1)</li> <li>Fludarabine 50mg/m2(Day -6,-5,-4,-3,-2),Busulfan 3.2mg/kg(Day -5,-4,-3,-2),400cGY Total Body Irradiation(TBI)Day-1,ATG 1.5mg/kg(Day-7,-5,-3,-1)</li> </ol> Day 0 -Haploidentical donor and one <b>umbilical cord blood</b> unit infusion Other Name: <b>Cord Blood</b> Transplant

**Detailed Description:**

This method of stem cell transplantation is designed to overcome some of the limitations of other alternative donor transplant options. Use of unrelated umbilical cord unit (UCB) donors appears to allow a greater degree of HLA mismatch with acceptable rates of GVHD. However, when UCB transplant was studied in the adult population, investigators discovered several limitations. One major limitation with UCB was delayed engraftment, resulting in higher risk of infection in the early post transplant period. The limitations to cord blood transplant involve delayed engraftment resulting in early complications such as infections. The main limitation associated with haploidentical donors is the significant immunosuppression required to prevent/treat aGVHD. Use of this combined modality of transplantation appears to allow for rapid neutrophil engraftment from the haploidentical donor and coupled with long term hematopoiesis from the UCB donor, thus requiring less long term immunosuppression.

This study tests a new method of bone marrow transplantation called combined haploidentical-cord blood transplantation. In this procedure, some of the blood forming cells (the stem cells) from a partially HLA matched (haploidentical) related donor are collected from the blood, as well as cells from an umbilical cord are transplanted into the patient (the recipient) after administration of a "conditioning regimen". A conditioning regimen consists of chemotherapy and sometimes radiation to the entire body (total body irradiation, or TBI),

One of two 'conditioning regimens' which will be determined by the physician.

- FLUDARABINE, MELPHALAN, ATG Fludarabine 30mg/m2(Days-7,-6,-5,-4,-3)-,Melphalan 70mg/m2(Day -3,-2), ATG 1.5mg/m2(Day-7,-5,-3,-1)
- FLUDARABINE, BUSULFAN, 400 CGY TBI, ATG Fludarabine 50mg/m2(Day -6,-5,-4,-3,-2),Busulfan 3.2mg/kg(Day -5,-4,-3,-2) 400cGY Total Body Irradiation(TBI)Day-1,ATG 1.5mg/kg(Day-7,-5,-3,-1)

Day 0 -Haploidentical donor and one umbilical cord blood unit infusion

Filgrastim will be administered daily from day +1 until blood counts have completely recovered. Tacrolimus and another immunosuppressant,

Cellcept, starting before transplant also to reduce the risks of graft versus host disease and to promote the growth of the graft. Tacrolimus will be given daily from two days before the transplant until at least three months after transplantation. Cellcept, will be tapered after the cells engraft.

## ► Eligibility

Ages Eligible for Study: 18 Years to 65 Years  
 Genders Eligible for Study: Both  
 Accepts Healthy Volunteers: No

### Criteria

#### Inclusion Criteria:

- Patients  $\geq$  18 years old
- Patient has a related family member(haploidentical) or unrelated which is 5 of 10 HLA identical match.

#### Standard Risk

- Acute myelogenous leukemia: CR1 with high risk cytogenetics or molecular abnormalities such as FLT-3 ITD, or CR2 with a first remission that must have lasted  $>$  1 year.
- Acute Lymphocytic Leukemia: CR1, in order to be standard risk must NOT have Philadelphia Chromosome.
- Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): Must be refractory to fludarabine or fail to have a complete or partial response after therapy with a regimen containing fludarabine (or another nucleoside analog, e.g. 2-CDA, pentostatin) or experience disease relapse within 12 months after completing therapy with a regimen containing fludarabine (or another nucleoside analog).
- Chronic myelogenous leukemia: resistant to or intolerant of TKI, in CP1 or CP2, or with a mutation that suggests resistance to TKI.
- Myelodysplastic Syndrome: RA, RARS, must be IPSS  $\geq$  INT-2, Blasts  $<$ 5%.

#### High Risk Patients:

- Acute myelogenous leukemia: Patients with CR2 are considered high risk if they have high risk cytogenetics, or molecular abnormalities or CR1 lasted for less than 1 year. Any evidence of active disease or no blasts in an acellular marrow.
- Acute Lymphocytic Leukemia: CR1- with Ph+ disease, CR2/+ with any cytogenetics. Any evidence of active disease.
- Chronic myelogenous leukemia- CP2/+, AP1/+, resistant or intolerant to TKI.
- Hodgkin's or Non Hodgkin's lymphoma- Disease recurrence following an autologous transplant, or high risk disease not thought to benefit from autologous transplant.
- Chronic lymphocytic leukemia- that is resistant to fludarabine, and never has been in remission or with stable disease/progressive disease
- Multiple myeloma: Must have had prior treatment. Patients with high risk cytogenetics in CR1 may be considered. Previous autologous transplant allowed, however, must have been greater than 6 months prior to undergoing this transplant.
- Myelodysplastic syndrome: RAEB, CMML
- Other Myeloproliferative disorders including myelofibrosis, spent phase p Vera or Essential thrombocytosis.

#### Exclusion Criteria:

- Patients  $<$ 18 years old Disease related criteria
- APLM, presence of t(15,17) in first CR
- Patients with good risk AML, for example t(8;21), or inv 16, or normal cytogenetics with FLT-3-ITD negative, NPM-1 positive disease in 1st CR
- MDS IPSS  $<$  INT-2 Miscellaneous Criteria
- Recipients who have a matched related sibling or unrelated donor
- If recipient has evidence of anti-HLA antibodies directed against cord or haplo-donor as determined byflowPRA.

#### Underlying health criteria:

- Zubrod performance status  $>$  2 (see Appendix E)
- Life expectancy is limited to less than 8 weeks by concomitant illness
- Patients with severely decreased LVEF (EF  $<$  40%)
- Impaired pulmonary function tests (PFT's) (FVC, FEV1, DLCO  $<$  45% predicted)
- Estimated Creatinine Clearance  $<$ 50 ml/min
- Serum bilirubin  $>$  2.0 mg/dl or SGPT  $>$ 3 x upper limit of normal
- Evidence of chronic active hepatitis or cirrhosis
- HIV-positive
- Patient is pregnant
- Patient or guardian not able to provide informed consent

## ► Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01050946

**Contacts**

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**Locations**

**United States, Wisconsin**

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 Milwaukee, Wisconsin, United States, 53226

**Sponsors and Collaborators**

Medical College of Wisconsin

**Investigators**

Principal Investigator: Jeanne Palmer, M.D. Medical College of Wisconsin

 **More Information**

No publications provided

Responsible Party: Jeanne Palmer, MD, Medical College of Wisconsin/Froedtert Hospital  
 ClinicalTrials.gov Identifier: [NCT01050946](#) [History of Changes](#)  
 Other Study ID Numbers: MCW 11491  
 Study First Received: January 14, 2010  
 Last Updated: January 15, 2010  
 Health Authority: United States: Institutional Review Board

Keywords provided by Medical College of Wisconsin:

Unrelated <b>Umbilical Cord Blood</b> Transplant(UCB)	AML
<b>Lymphoma, Hodgkins</b>	Leukemia, Myelocytic, Acute
CD34+ Selected mismatched related donor	CML
Haploidentical donor	Leukemia, Myeloid, Chronic
hematopoietic stem cell transplantation(HSCT)	NHL
ALL	Lymphoma, Non-Hodgkin
Leukemia, Lymphocytic, Acute	HL

Additional relevant MeSH terms:

<b>Hodgkin Disease</b>	Leukemia, Lymphoid
Lymphoproliferative <b>Disorders</b>	Precursor Cell Lymphoblastic Leukemia-Lymphoma
Lymphatic <b>Diseases</b>	Leukemia, Myeloid, Acute
Immunoproliferative <b>Disorders</b>	Leukemia, Myeloid
Immune System <b>Diseases</b>	Leukemia, Myelogenous, Chronic, BCR-ABL Positive
Myeloproliferative <b>Disorders</b>	Lymphoma
Bone Marrow <b>Diseases</b>	Lymphoma, Non-Hodgkin
Hematologic <b>Diseases</b>	Neoplasms by Histologic Type
Leukemia	Neoplasms
Leukemia, Lymphocytic, Chronic, B-Cell	Leukemia, B-Cell

ClinicalTrials.gov processed this record on September 22, 2013