

Trial record **5 of 9** for: umbilical cord blood and fanconi anemia
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Cord Blood Stem Cell Transplantation Study (COBLT)

This study has been completed.

Sponsor:

National Heart, Lung, and Blood Institute (NHLBI)

Information provided by:

National Heart, Lung, and Blood Institute (NHLBI)

ClinicalTrials.gov Identifier:

NCT00000603

First received: October 27, 1999

Last updated: January 18, 2008

Last verified: January 2008

[History of Changes](#)

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► Purpose

To evaluate if HLA-mismatched, unrelated-donor **umbilical cord blood** stem and progenitor cell units (UCBU) offered a clinically acceptable alternative to matched unrelated-donor allogeneic bone marrow for transplantation with 180-day disease free survival as the endpoint. HLA typing was performed using DNA-base high resolution methods to determine HLA alleles. Patients with "true" HLA 3/6 and 4/6 matches were evaluated. In addition, a separate study in adults addressed the problem of limited cell dose and engraftment failure. The study was not planned as a randomized comparative clinical trial. Instead, it is a phase II/III efficacy study.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Anemia , Aplastic Fanconi Anemia Hematologic Diseases Leukemia Neoplasms Severe Combined Immunodeficiency Hematopoietic Stem Cell Transplantation Myelodysplastic Syndromes	Procedure: stem cell transplantation	Phase 2

Study Type: Interventional

Study Design: Primary Purpose: Treatment

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [adenosine deaminase deficiency](#) [complement factor I deficiency](#) [Fanconi anemia](#) [purine nucleoside phosphorylase deficiency](#) [X-linked severe combined immunodeficiency](#) [ZAP70-related severe combined immunodeficiency](#)

[MedlinePlus](#) related topics: [Anemia](#) [Aplastic Anemia](#) [Blood Disorders](#) [Cancer](#) [Leukemia](#) [Myelodysplastic Syndromes](#)

[U.S. FDA Resources](#)

Further study details as provided by National Heart, Lung, and Blood Institute (NHLBI):

Study Start Date: September 1996

Study Completion Date: October 2007

Primary Completion Date: October 2007 (Final data collection date for primary outcome measure)

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► Eligibility

Ages Eligible for Study: up to 55 Years
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Mothers of Infant-donors must complete a medical history form, have an uncomplicated delivery, and deliver at UCLA or Duke.

Patients are those who need a transplant but don't have a matched marrow donor or can't wait to find one.

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00000603

Sponsors and Collaborators

National Heart, Lung, and Blood Institute (NHLBI)

Investigators

Investigator: Shelly Carter The EMMES Corporation

Investigator: Joanne Kurtzberg Duke University

▶ More Information

Additional Information:

[Related Info](#) [EXIT](#)

Publications:

[Wagner JE, Kurtzberg J. Banking and transplantation of unrelated donor umbilical cord blood: status of the National Heart, Lung, and Blood Institute-sponsored trial. Transfusion. 1998 Sep;38\(9\):807-9. Review. No abstract available.](#)

[Fraser JK, Cairo MS, Wagner EL, McCurdy PR, Baxter-Lowe LA, Carter SL, Kernan NA, Lill MC, Slone V, Wagner JE, Wallas CH, Kurtzberg J. Cord Blood Transplantation Study \(COBLT\): cord blood bank standard operating procedures. J Hematother. 1998 Dec;7\(6\):521-61. Review.](#)

[Laughlin MJ, Barker J, Bambach B, Koc ON, Rizzieri DA, Wagner JE, Gerson SL, Lazarus HM, Cairo M, Stevens CE, Rubinstein P, Kurtzberg J. Hematopoietic engraftment and survival in adult recipients of umbilical-cord blood from unrelated donors. N Engl J Med. 2001 Jun 14;344\(24\):1815-22.](#)

[Barker JN, Wagner JE. Umbilical cord blood transplantation: current practice and future innovations. Crit Rev Oncol Hematol. 2003 Oct;48\(1\):35-43.](#)

[Staba SL, Escolar ML, Poe M, Kim Y, Martin PL, Szabolcs P, Allison-Thacker J, Wood S, Wenger DA, Rubinstein P, Hopwood JJ, Krivit W, Kurtzberg J. Cord-blood transplants from unrelated donors in patients with Hurler's syndrome. N Engl J Med. 2004 May 6;350\(19\):1960-9.](#)

[Laughlin MJ, Eapen M, Rubinstein P, Wagner JE, Zhang MJ, Champlin RE, Stevens C, Barker JN, Gale RP, Lazarus HM, Marks DI, van Rood JJ, Scaradavou A, Horowitz MM. Outcomes after transplantation of cord blood or bone marrow from unrelated donors in adults with leukemia. N Engl J Med. 2004 Nov 25;351\(22\):2265-75.](#)

[Cornetta K, Laughlin M, Carter S, Wall D, Weinthal J, Delaney C, Wagner J, Sweetman R, McCarthy P, Chao N. Umbilical cord blood transplantation in adults: results of the prospective Cord Blood Transplantation \(COBLT\). Biol Blood Marrow Transplant. 2005 Feb;11\(2\):149-60.](#)

[Wall DA, Carter SL, Kernan NA, Kapoor N, Kamani NR, Brochstein JA, Frangoul H, Goyal RK, Horan JT, Pietryga D, Wagner JE, Kurtzberg J. Busulfan/Melphalan/Antithymocyte Globulin Followed by Unrelated Donor Cord Blood Transplantation for Treatment of Infant Leukemia and Leukemia in Young Children: The Cord Blood Transplantation Study \(COBLT\) Experience. Biol Blood Marrow Transplant. 2005 Aug;11\(8\):637-46.](#)

[Cairo MS, Wagner EL, Fraser J, Cohen G, van de Ven C, Carter SL, Kernan NA, Kurtzberg J. Characterization of banked umbilical cord blood hematopoietic progenitor cells and lymphocyte subsets and correlation with ethnicity, birth weight, sex, and type of delivery: a Cord Blood Transplantation \(COBLT\) Study report. Transfusion. 2005 Jun;45\(6\):856-66.](#)

[Kurtzberg J, Cairo MS, Fraser JK, Baxter-Lowe L, Cohen G, Carter SL, Kernan NA. Results of the cord blood transplantation \(COBLT\) study unrelated donor banking program. Transfusion. 2005 Jun;45\(6\):842-55.](#)

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

[Kurtzberg J, Prasad VK, Carter SL, Wagner JE, Baxter-Lowe LA, Wall D, Kapoor N, Guinan EC, Feig SA, Wagner EL, Kernan NA; COBLT](#)

[Steering Committee. Results of the Cord Blood Transplantation Study \(COBLT\): clinical outcomes of unrelated donor umbilical cord blood transplantation in pediatric patients with hematologic malignancies. Blood. 2008 Nov 15;112\(10\):4318-27. Epub 2008 Aug 21.](#)

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Other Study ID Numbers: 316
Study First Received: October 27, 1999
Last Updated: January 18, 2008
Health Authority: United States: Federal Government

Additional relevant MeSH terms:

Anemia	Bone Marrow Diseases
Anemia , Aplastic	Genetic Diseases, Inborn
Fanconi Anemia	DNA Repair-Deficiency Disorders
Fanconi Syndrome	Metabolic Diseases
Anemia , Hypoplastic, Congenital	Kidney Diseases
Neoplasms	Urologic Diseases
Hematologic Diseases	Renal Tubular Transport, Inborn Errors
Immunologic Deficiency Syndromes	Metabolism, Inborn Errors
Leukemia	Immune System Diseases
Myelodysplastic Syndromes	Neoplasms by Histologic Type
Preleukemia	Precancerous Conditions
Severe Combined Immunodeficiency	Infant, Newborn, Diseases

ClinicalTrials.gov processed this record on September 22, 2013