Cord Blood for Neonatal Hypoxic-ischemic Encephalopathy

This study is currently recruiting participants.
Verified October 2013 by Duke University
Sponsor:
Michael Cotten
Information provided by (Responsible Party):
Michael Cotten, Duke University Medical Center
ClinicalTrials.gov Identifier:
NCT00593242
First received: January 2, 2008
Last updated: October 17, 2013
Last verified: October 2013
History of Changes

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

Purpose

This is a pilot study to test feasibility of collection, preparation and infusion of a baby's own (autologous)umbilical cord blood in the first 14 days after birth if the baby is born with signs of brain injury.

Condition	Intervention	Phase
Neonatal Hypoxic Ischemic Encephalopathy	Biological: infusion of autologous cord blood Other: Neurodevelopmental outcomes	Phase 1

Study Type: Interventional

Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label

Primary Purpose: Treatment

Official Title: Autologous Cord Blood Cells for Hypoxic Ischemic Encephalopathy Study 1. Phase I Study of Feasibility and Safety.

Resource links provided by NLM:

Genetic and Rare Diseases Information Center resources: Hepatic Encephalopathy Neurotoxicity Syndromes

U.S. FDA Resources

Further study details as provided by Duke University:

Primary Outcome Measures:

- Adverse event rates occurring in the pilot study population will be compared between the cord blood cell recipients and historical controls. [Time Frame: during infusions: first 18 postnatal days] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Secondary endpoints of this pilot study will include preliminary efficacy as measured by neurodevelopmental function at 4 - 6 months and 9 - 12 months of age [Time Frame: 1 year] [Designated as safety issue: No]
- neuroimaging results will be collected and compared with available results from prior trials of therapies in this population, and from a previously collected set of images from normal term newborns through the first year of life. [Time Frame: 6 months] [Designated as safety issue: No]

Estimated Enrollment: 25

Study Start Date: January 2008

Estimated Study Completion Date: June 2014

Estimated Primary Completion Date: June 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: infusions infants who arrive at the study site within the	Biological: infusion of autologous cord blood infants who meet study enrollment criteria for

first 14 postnatal days and had a history of moderate to severe hypoxic ischemic encephalopathy, and have cells available for infusion that pass Carolinas Cord Blood Bank Quality checks Outcomes will be measured at 22-26 months fby neurodevelopment assessment	history of moderate to severe hypoxic ischemic encephalopathy in the neonatal period will receive up to 4 infusions of their own volume reduced cord blood cells. The number of doses will be determined by the amount of available cord blood cells. The dose for each infusion is 5x10e7 cells/kg
historical control Infants who had moderate to severe hypoxic ischemic encephalopathy in the neonatal period but did not receive autologous cord blood cells.	Other: Neurodevelopmental outcomes historical controls, no experimental intervention, standard therapies of hypoxic ischemic encephalopathy in the newborn period with autologous cord blood

Detailed Description:

The purpose of this pilot study is to evaluate the safety and feasibility of infusions of autologous (the patient's own)umbilical cord blood cells in term gestation newborn infants with hypoxic-ischemic encephalopathy. For this study, infants who have signs of moderate to severe encephalopathy at birth whose mothers have previously consented to providing cord blood cells for the Carolinas Cord Blood Bank or other public or private bank that uses accepted standards for collection and handling of cells, or provided verbal consent for cord blood collection for the possibility of their baby's participation in this trial, can receive their own cord blood cells if an adequate number of cells that meet Carolinas Cord Blood Bank Quality standards are available in the first 14 postnatal days. Study activities also include serial blood draws concurrent with clinically indicated blood draws with a total volume of no more than 5 milliliters (1 teaspoon) from all study related tests. Babies will be followed for neurodevelopmental outcome at 4 - 6 and 9 - 12 months at Duke's Special Infant Care Clinic. MRI's will be obtained per clinical routine and results will be analyzed and described in study reports.

Eligibility

Ages Eligible for Study: up to 14 Days
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Criteria
Inclusion Criteria:

- Mothers must have consented for cord blood collection at delivery
- cord blood must be available for extraction of stem cells.
- >34 weeks gestation
- cord or neonatal pH<7.0 or base deficit>16 milliequivalents per liter (mEq/L) or history of acute perinatal event
- either a 10 minute Apgar < 5 or continued need for ventilation.
- All infants must have signs of encephalopathy within 6 hours of age.

Exclusion Criteria:

- Inability to enroll by 14 days of age.
- Presence of known chromosomal anomaly.
- Presence of major congenital anomalies.
- Severe intrauterine growth restriction (weight <1800g)
- Infants in extremis for whom no additional intensive therapy will be offered by attending neonatologist.
- Parents refuse consent.
- Attending neonatologist refuses consent.
- Failure to collect the infant's cord blood and/or laboratory unable to process cord blood.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00593242

Contacts

Contact: Kimberley A Fisher, PhD 919-681-4913 kimberley.fisher@duke.edu

Contact: Charles M Cotten, MD MHS 919-681-4844 cotte010@mc.duke.edu

Locations

United States, North Carolina

Duke University Recruiting
Durham, North Carolina, United States, 27710
Contact: Kimberley A Fisher, PhD 919-681-4913 kimberley.fisher@duke.edu
Sub-Investigator: Joanne Kurtzberg, MD
Sub-Investigator: Allen Song, PhD
Sub-Investigator: Ricki Goldstein, MD
Sub-Investigator: Ronald Goldberg, MD
Sub-Investigator: James Provenzale, MD

Sponsors and Collaborators

Michael Cotten

Investigators

Principal Investigator: Charles M Cotten, MD MHS Duke University

More Information

Additional Information:

Carolinas Cord Blood Bank web page EXIT

Publications:

Martin PL, Carter SL, Kernan NA, Sahdev I, Wall D, Pietryga D, Wagner JE, Kurtzberg J. Results of the cord blood transplantation study (COBLT): outcomes of unrelated donor umbilical

cord blood transplantation in pediatric patients with lysosomal and peroxisomal storage diseases. Biol Blood Marrow Transplant. 2006 Feb;12(2):184-94.
Kurtzberg J, Lyerly AD, Sugarman J. Untying the Gordian knot: policies, practices, and ethical issues related to banking of umbilical cord blood. J Clin Invest. 2005 Oct;115(10):2592-7. Review.
Escolar ML, Poe MD, Provenzale JM, Richards KC, Allison J, Wood S, Wenger DA, Pietryga D, Wall D, Champagne M, Morse R, Krivit W, Kurtzberg J. Transplantation of umbilical-cord blood in babies with infantile Krabbe's disease. N Engl J Med. 2005 May 19;352(20):2069-81.
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.
McGraw P, Liang L, Escolar M, Mukundan S, Kurtzberg J, Provenzale JM. Krabbe disease treated with hematopoietic stem cell transplantation: serial assessment of anisotropy measurements--initial experience. Radiology. 2005 Jul;236(1):221-30.

Responsible Party:	Michael Cotten, Associate Professor of Pediatrics, Duke University Medical Center
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Health Authority:	United States: Institutional Review Board United States: Food and Drug Administration

Keywords provided by Duke University:
hypoxic-ischemic encephalopathy
autologous cord blood cells
newborn infants

Additional relevant MeSH terms:

Hypoxia-Ischemia, Brain	Pathologic Processes
Hypoxia, Brain	Confusion
Brain Ischemia	Neurobehavioral Manifestations
Ischemia	Neurologic Manifestations
Brain Damage, Chronic	Signs and Symptoms
Delirium	Delirium, Dementia, Amnestic, Cognitive Disorders
Encephalitis	Mental Disorders
Hepatic Encephalopathy	Central Nervous System Viral Diseases
Neurotoxicity Syndromes	Virus Diseases
Cerebrovascular Disorders	Central Nervous System Infections
Brain Diseases	Liver Failure
Central Nervous System Diseases	Hepatic Insufficiency
Nervous System Diseases	Liver Diseases
Vascular Diseases	

Cardiovascular Diseases

Digestive System Diseases
Brain Diseases, Metabolic

ClinicalTrials.gov processed this record on February 27, 2014