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Safety Study of Umbilical Cord Blood To Treat Pediatric Traumatic Brain Injury

This study is currently recruiting participants.

Verified August 2013 by The University of Texas Health Science Center, Houston

Sponsor:
Charles Cox

Information provided by (Responsible Party):
Charles Cox, The University of Texas Health Science Center, Houston

ClinicalTrials.gov Identifier:
NCT01251003

First received: November 29, 2010
Last updated: August 28, 2013
Last verified: August 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	November 29, 2010
Last Updated Date	August 28, 2013
Start Date ICMJE	January 2011
Estimated Primary Completion Date	December 2014 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: November 30, 2010)**	Determine if autologous hUCB transplantation is safe and free of infusion related toxicity. [Time Frame: 0-21 days post cellular product infusion] [Designated as safety issue: Yes]
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT01251003 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: November 30, 2010)**	Determine if autologous hUCB transplantation improves post-TBI neuropsychological and imaging outcomes measures. [Time Frame: 6 months, 12 months, 24 months post cellular product infusion] [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	Safety Study of Umbilical Cord Blood To Treat Pediatric Traumatic Brain Injury
Official Title ICMJE	Safety of Autologous Human Umbilical Cord Blood Treatment for Traumatic Brain in Children
Brief Summary	The purpose of this study is to determine if it is safe to use stored autologous Human Umbilical Cord Blood (hUCB) to treat pediatric patients that sustain a severe or moderate Traumatic Brain Injury (TBI), and have not fully recovered as measured by the Glasgow Outcome Score-Expanded (GOS-EC)/Child at 6 to 18 months post-injury.

Detailed Description	Traumatic brain injury is the primary cause of pediatric trauma related morbidity and mortality. Currently there is no reparative therapeutic option available, and all interventions are designed to prevent injury progression or secondary brain injury. Pre-clinical data suggest that progenitor cellular infusions may reduce the severity of injury by a number of proposed mechanisms. The current study proposes a Phase 1 Safety Trial using stored autologous UCB to treat patients that sustain a severe or moderate TBI, and have not fully recovered as measured by the Glasgow Outcome Score-Expanded/Child at 6 to 18 months post-injury. We have chosen to use one bank that uses standardized processing and storage protocol to reduce cell product variability. Families who have banked hUCB at Cord Blood Registry, Inc. (CBR), will be prospectively notified of the possibility of using their child's stored UCB if they sustain a moderate or severe TBI and have a persistent deficit at 6-18 months. Prior to enrolling in the study, patients will have their medical records, imaging studies reviewed, and a telephone interview will determine potential eligibility and exclusion criteria. If eligible, the patients will travel to Houston to undergo a medical history and physical exam, neuropsychiatric evaluation, DT-MRI imaging of the brain, and baseline laboratory evaluation. The UCB will be shipped to the Center for Cell and Gene Therapy for reanimation and characterization/determination of release criteria of the cell product (contamination-free). The UCB will be infused intravenously and the patient will be monitored as an in-patient in the Pediatric Intensive Care Unit (PICU) located within Children's Memorial Hermann Hospital for 24 hours, after which the patient will be discharged but will return the next day for a final examination. Follow-up visits will occur back at UT-Houston at 180 days, 1 year and 2 years post-infusion - these visits will include medical history and physical exam, neurological and neuropsych evaluations, and DT-MRI imaging of the brain.
Study Type ICMJE	Interventional
Study Phase	Phase 1 Phase 2
Study Design ICMJE	Endpoint Classification: Safety/Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
Condition ICMJE	Traumatic Brain Injury
Intervention ICMJE	Biological: Autologous cord blood there is no minimum acceptable dose, and the maximum allowable dose will be 10x10(9)cells/kg given IV (in the vein), one time infusion
Study Arm (s)	*Not Provided*
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Recruiting
Estimated Enrollment ICMJE	10
Estimated Completion Date	December 2015
Estimated Primary Completion Date	December 2014 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: • Hospital admission Glasgow Coma Score between 3 and 12 at the time of injury • Injury occurring 6 to 18 months prior to study cord blood infusion (+/- 30 days) • Ability of child and caregiver to travel to Houston, and stay for at least 4 days, and to return for all Follow-up visits • Ability of child to understand (and speak) English • Child's own cord blood banked at Cord Blood Registry

	Exclusion Criteria: • Inability to obtain all pertinent medical records, including pertinent physician notes, laboratory findings, and radiographic images, related to the original injury, hospitalization and rehabilitation • Recent radiographic evidence of extensive stroke as evidenced by >100ml lesion • Pre-injury history of seizure disorder and/or neurological impairment • Obliteration of perimesencephalic cistern on initial head CT/MRI • Initial hospital Intracranial Pressure (ICP) > 40 • Unhealed fractures or wounds including osteomyelitis • Pneumonia, or chronic lung disease requiring oxygen • Spinal cord injury as diagnosed by CT or MR imaging or by clinical findings • Cord blood sample contamination • Participation in a concurrent intervention study
Gender	Both
Ages	18 Months to 17 Years
Accepts Healthy Volunteers	No
Contacts ICMJE	Contact: Steven C Kosmach, MSN, RN, CCRC — 713-500-7329 — steven.kosmach@uth.tmc.edu Contact: Fernando Jimenez, MS, RN — 713-500-7395 — fernando.jimenz@uth.tmc.edu
Location Countries ICMJE	United States

Administrative Information

NCT Number ICMJE	NCT01251003
Other Study ID Numbers ICMJE	HSC-MS-10-0061
Has Data Monitoring Committee	Yes
Responsible Party	Charles Cox, The University of Texas Health Science Center, Houston
Study Sponsor ICMJE	Charles Cox
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	Principal Investigator: Charles S Cox, Jr., MD — University of Texas Medical School at Houston
Information Provided By	The University of Texas Health Science Center, Houston
Verification Date	August 2013

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**