# 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

## Tracking Information

<table>
<thead>
<tr>
<th>Tracking Information</th>
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<tbody>
<tr>
<td>First Received Date</td>
<td>November 29, 2010</td>
</tr>
<tr>
<td>Last Updated Date</td>
<td>August 28, 2013</td>
</tr>
<tr>
<td>Start Date</td>
<td>January 2011</td>
</tr>
<tr>
<td>Estimated Primary Completion Date</td>
<td>December 2014 (final data collection date for primary outcome measure)</td>
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<tr>
<td>Current Primary Outcome Measures</td>
<td>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 ]</td>
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<td>Original Primary Outcome Measures</td>
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<tr>
<td>Change History</td>
<td>Complete list of historical versions of study NCT01251003 on ClinicalTrials.gov Archive Site</td>
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<tr>
<td>Current Secondary Outcome Measures</td>
<td>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 ]</td>
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<td>Original Secondary Outcome Measures</td>
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<td>Current Other Outcome Measures</td>
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<td>Original Other Outcome Measures</td>
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## Descriptive Information

<table>
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<tr>
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<tbody>
<tr>
<td>Brief Title</td>
<td>Safety Study of Umbilical Cord Blood To Treat Pediatric Traumatic Brain Injury</td>
</tr>
<tr>
<td>Official Title</td>
<td>Safety of Autologous Human Umbilical Cord Blood Treatment for Traumatic Brain in Children</td>
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<tr>
<td>Brief Summary</td>
<td>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.</td>
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### 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

Interventional

### Study Phase

Phase 1

### Study Design

Endpoint Classification: Safety/Efficacy Study

- Intervention Model: Single Group Assignment
- Masking: Open Label
- Primary Purpose: Treatment

### Condition

Traumatic Brain Injury

### Intervention

Biological: Autologous cord blood

- there is no minimum acceptable dose, and the maximum allowable dose will be $10 \times 10^9$ 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

Recruiting

#### Estimated Enrollment

10

#### Estimated Completion Date

December 2015

#### Estimated Primary Completion Date

December 2014 (final data collection date for primary outcome measure)

#### Eligibility 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

<table>
<thead>
<tr>
<th>Gender</th>
<th>Both</th>
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<tbody>
<tr>
<td>Ages</td>
<td>18 Months to 17 Years</td>
</tr>
<tr>
<td>Accepts Healthy Volunteers</td>
<td>No</td>
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</table>
| Contacts     | **Contact**: Steven C Kosmach, MSN, RN, CCRC 713-500-7329  
**Contact**: Fernando Jimenez, MS, RN 713-500-7395  |
| Location Countries | United States                             |

## Administrative Information
- **NCT Number**: NCT01251003
- **Other Study ID Numbers**: HSC-MS-10-0061
- **Has Data Monitoring Committee**: Yes
- **Responsible Party**: Charles Cox, The University of Texas Health Science Center, Houston
- **Study Sponsor**: Charles Cox
- **Collaborators**: Not Provided
- **Investigators**
  - **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

*Data element required by the [International Committee of Medical Journal Editors](https://www.icmje.org) and the [World Health Organization ICTRP](https://www.who.int/ictrp/en)*