

Cerebral Palsy – Autologous Cord Blood Study

Duke University Medical Center is conducting a study to test whether an intravenous infusion of a child's own cord blood cells, banked at the time of their birth, will lessen the symptoms of cerebral palsy. Children, ages 12 months to 6 years, diagnosed with spastic cerebral palsy may be eligible for the study if their cord blood cells were banked when they were born. The study is a randomized, placebo-controlled, crossover trial which means that children will receive either cells or a mock infusion of a harmless liquid and that no one involved with the child's care will know when they actually receive their cells. Some children will receive cells at the beginning of the study and others will receive cells one year later. All children will be evaluated at the beginning of the study and 1 and 2 years later.

A child's eligibility will be determined in consultation with the study team at Duke. To determine initial eligibility, information about the child's cord blood and a blood test on the child and the cord blood will need to be performed to confirm that the cord blood is the one belonging to the child and that the cells are healthy. These tests are not part of the study. If, after review of these test results and through phone and email consultation with the study team, the child is eligible for the study, appointments will be arranged at Duke for evaluation by the transplant team, a pediatric neurologist and developmental specialists, an MRI and an infusion of either cells or a placebo. All treatment is conducted in the clinic at Duke. One year later, the child will return for repeat evaluations and a second infusion. Children will cross over and receive whichever product they did not receive during their first infusion. The risks of this study include placement of an intravenous line (IV), possible sedation for the MRI and infection or allergic reactions due to infusion of the cord blood.

The costs of the evaluations and cell infusions will be covered by the study. There will be a small supplement provided to families to help support the costs of travel and lodging, but the supplement may not cover all of the costs for these activities. The study will be completed within 3 years of its starting date and results will be published in peer-reviewed medical journals.

For more information about this study, please call the Duke Pediatric Blood and Marrow Transplant Program at (919) 668-1100 or email Dr. Jessica Sun at jessica.sun@duke.edu. Study information is also available online at clinicaltrials.gov.

