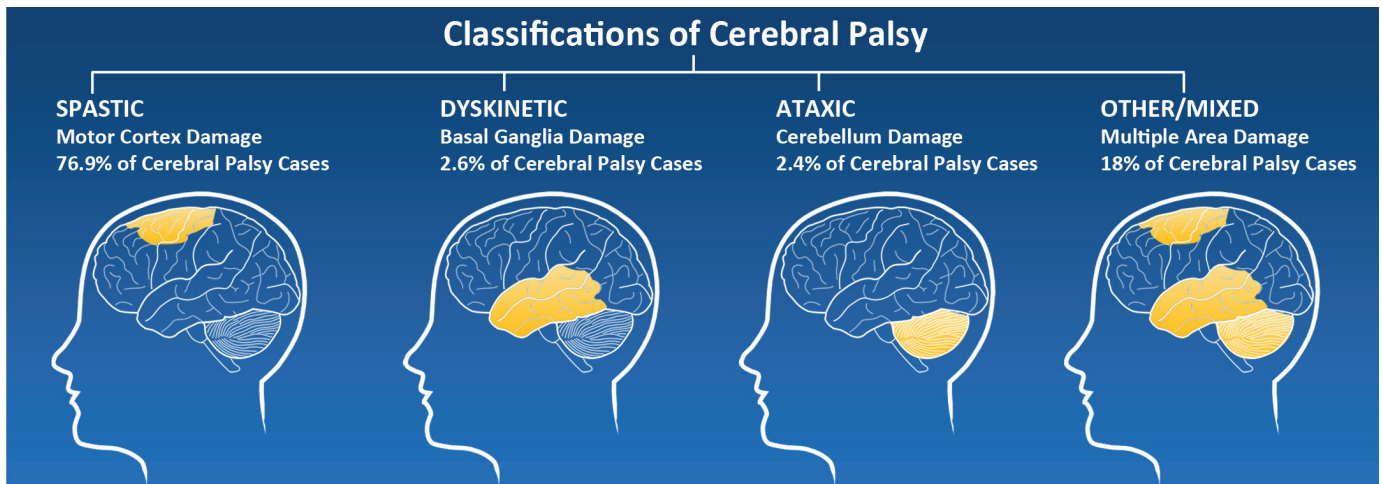




Disease: Cerebral Palsy

Cerebral Palsy

Cerebral Palsy (CP) is a motor disability that affects a person's ability to move and maintain balance and posture. It is usually caused, before the baby is born, by an abnormality or disruption in brain development in the portion of the brain that controls muscle tone. In many cases, the precise trigger for this abnormality is unknown; however, factors that may lead to problems with brain development include oxygen deprivation, fetal stroke, maternal infections, traumatic brain injury and genetic mutations. Premature babies (born before 37 weeks) and babies with low birth weight (less than 2.5 kg) are at a greater risk of developing CP.



Prevalence of Cerebral Palsy in 8-Year-Old Children in Three Areas of the United States in 2002: A Multisite Collaboration. PEDIATRICS Volume 121, Number 3, March 2008 (pg 547-554).

Incidence

Cerebral Palsy occurs in 3.1 to 3.6 out of every 1,000 children (Reference: Prevalence of Four Developmental Disabilities Among Children Aged 8 Years – Metropolitan Atlanta Developmental Disabilities Surveillance Program, 1996 and 2000. Bhasin TK, Brocksen S, Avchen RN, Van Naarden Braun K. MMWR(TM) Surveillance Summaries. January 27, 2006. 55(SS01); 1-9).

Impact of Umbilical Cord Blood

Pioneering work treating CP patients with their own cord blood was conducted at Duke University by Dr. Joanne Kurtzberg. Results from this early study suggested that cord blood therapy improved the condition of patients with CP. The FDA has approved Dr. Kurtzberg's second CP clinical trial, which is designed to provide objective data on the effect of cord blood on the clinical outcome of the CP patients. Patients in this study will be between the ages of 1 and 6 years, with spastic CP. They will be children whose parents elected to bank their children's cord blood at delivery.

Another CP trial is being conducted at the Medical College of Georgia, by Dr. James Carroll. The purpose of this study is similar to Dr. Kurtzberg's first trial, to test the safety and effectiveness of a cord blood infusion in children with CP. Again, patients in this study will be children whose parents banked their children's cord blood. Success in these trials would offer hope to patients suffering from CP, a currently incurable disorder.

A Randomized Study of Autologous Umbilical Cord Blood Reinfusion in Children with Cerebral Palsy

Background

Sponsors and Collaborators: Joanne Kurtzberg, Roberson Foundation (funding) Condition: Cerebral Palsy, CP, Spastic Cerebral Palsy

Intervention: Biological – Autologous Umbilical Cord Blood or Placebo

Stage: Phase 2

Study Start Date: June 2010

Estimated Study Completion Date: January 2016

Source: <http://clinicaltrials.gov/ct2/show/NCT01147653>

Purpose

The purpose of this study is to determine the efficacy of a single intravenous infusion of autologous umbilical cord blood (UCB) for the treatment of pediatric patients with spastic Cerebral Palsy.

Detailed Description

Cerebral Palsy results from in utero or perinatal injury to the developing brain, often through stroke, hypoxic insult or hemorrhage. Currently available treatments for patients with Cerebral Palsy are supportive, but not curative. Umbilical cord blood (UCB) has been shown to lessen the clinical and radiographic impact of hypoxic brain injury and stroke in animal models. UCB also engrafts and differentiates in the brain, facilitating neural cell repair, in animal models and human patients with inborn errors of metabolism undergoing allogeneic, unrelated donor UCB transplantation. We hypothesize that, in the setting of brain injury, infusion of autologous UCB will facilitate neural cell repair resulting in improved function in pediatric patients with Cerebral Palsy.

Study Design

All participants will be treated with autologous cord blood reinfusion, but the time course will vary between groups and participants will be blinded to the order in which they receive infusions. Patients will be randomized to receive their autologous umbilical cord blood cells first or placebo first. Subjects will receive both infusions; but they will be randomized and blinded by which one they are receiving first and second.

Related clinical trials of interest

Georgia Regents University: Safety and Effectiveness of Cord Blood Stem Cell Infusion for the Treatment of Cerebral Palsy in Children (<http://clinicaltrials.gov/show/NCT01072370>).

Hospital Universitario Dr. Jose E. Gonzalez: Autologous Stem Cells in Newborns With Oxygen Deprivation (<http://clinicaltrials.gov/show/NCT01506258>).