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MCG to conduct first FDA-approved stem cell trial in pediatric cerebral palsy

AUGUSTA, Ga. – February 11, 2010 -- Medical College of Georgia researchers are conducting the first FDA-approved clinical trial to determine whether an infusion of stem cells from umbilical cord blood can improve the quality of life for children with cerebral palsy.

The study will include 40 children age 2-12 whose parents have stored cord blood at the Cord Blood Registry in Tucson, Ariz.

Umbilical cord blood is rich in stem cells, which can divide and morph into different types of cells throughout the body, said Dr. James Carroll, professor and chief of pediatric neurology in MCG School of Medicine and principal investigator on the study.

Cerebral palsy, caused by a brain injury or lack of oxygen in the brain before birth or during the first few years of life, can impair movement, learning, hearing, vision and cognitive skills. Two to 3 children in 1,000 are affected by it, according to the Centers for Disease Control.

Animal studies indicate that infused stem cells help injured brain cells recover and replace brain cells that have died, Dr. Carroll said.

“Autologous stem cell transplantation, in which the transplant recipient is also the donor, is the safest form of stem cell transplantation because it carries virtually no threat of immune system rejection,” he said.

While no controlled clinical trials have been conducted to date, previous studies have shown marked improvement in children with cerebral palsy about three months after an initial infusion of cord blood.

“Evidence up to this point has been purely anecdotal,” Dr. Carroll said. “While a variety of cord blood stem cell therapies have been used successfully for more than 20 years, this study is breaking new ground in advancing therapies for brain injury – a condition for which there is currently no cure.”

Children will begin the study with a neurological exam. Then, half of the study participants will receive an infusion of their own cord blood while the other half receive a placebo. Three months later, the children will be evaluated without physicians knowing which group received the stem cell infusion. Afterward, children who didn't get the cord blood initially will receive an infusion. Children will return three and six months later for evaluation.

Researchers will periodically assess the children's motor skills and neurological development.

“For the purposes of this study, we're not looking at stem cells as a possible cure; rather whether stem cells can help change the course of these types of brain injuries in children,” Dr. Carroll said.

Study participants must have been unable to sit independently by 12 months or unable to walk by 18 months and must be seizure-free or have seizures that are adequately controlled.

To ensure consistency in cord blood stem cell processing, storage and release for infusion, the Cord Blood Registry is the only family stem cell bank participating in the study. For more information, call the MCG Section of Pediatric Neurology at 706-721-3371.

The trial is also receiving support from the Associazione Figli Inabili Banca d'Italia, a private organization in Italy that provides financial assistance to parents who can't pay for their children's medical treatments on their own.

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