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Type 1 diabetes patients sought for UT Southwestern clinical drug trial

DALLAS – March 3, 2009 – UT Southwestern Medical Center researchers are recruiting individuals newly diagnosed with type 1 diabetes for a clinical trial to gauge the effectiveness of adding an investigational stem cell product to standard insulin therapy.

In type 1 diabetes, formerly known as juvenile-onset diabetes, the pancreatic beta cells that produce insulin are destroyed by an autoimmune process. Type 1 diabetics must regiment their diets and take insulin multiple times a day to control blood sugar levels and prevent diabetic coma. In the U.S. the autoimmune disease affects about 1 million people. There is no known cure.

Dr. Philip Raskin, professor of internal medicine at UT Southwestern and principal investigator of the trial's local effort, said the multicenter study aims to determine whether an investigational drug called Prochymal can be used to treat patients newly diagnosed with type 1 diabetes in addition to their usual insulin dose.

"Our hope is that the infusion of these adult stems cells will help stabilize the pancreatic beta cells so that they continue to produce insulin," said Dr. Raskin. "This is by no means a cure for type 1 diabetes, but our hope is that the addition of these stem cells could make the disease more easily managed."

Prochymal, developed by Osiris Therapeutics, is a formulation of adult mesenchymal stem cells designed to control inflammation, promote tissue regeneration and prevent scar formation. These cells, which can develop into bone, muscle and fat, are derived solely from healthy, adult volunteer bone marrow donors. Studies have shown that adult mesenchymal stem cells have a very low risk of rejection, similar to blood type O, the universal donor type.

The formulation to be evaluated in the UT Southwestern study is currently in expanded human clinical trials for graft-versus-host-disease and Crohn's disease but this is the first time it will be tested in patients with type 1 diabetes.

Research has shown that when adult mesenchymal stem cells are injected into an animal, the cells home in on and begin to repair any damaged tissues. If there is no damage, the stem cells return to the bone marrow.

(MORE)

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Dr. Raskin said that while Prochymal has not been investigated in patients with type 1 diabetes, he believes that the stem cells will target the pancreas because of the inflammation and tissue damage caused by the autoimmune process.

For the clinical study, 60 participants will be randomly assigned to receive either the stem cell formulation or a placebo. About 10 individuals will participate at UT Southwestern, the only study site in the southwestern U.S.

Study participants will have their blood drawn eight times over a two-year period. The study agent or placebo will be given through an infusion during the first three visits.

To be eligible for the initial screening, you must be between the ages of 18 and 30 and have been diagnosed with type 1 diabetes within the past 16 weeks.

The study is funded by the Juvenile Diabetes Research Foundation and Osiris Therapeutics.

For more information about the clinical trial, call 214-648-4716.

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