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Study to determine whether leptin helps type 1 diabetes patients

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A clinical trial at UT Southwestern Medical Center aims to determine whether adding the hormone leptin to standard insulin therapy might help rein in the tumultuous blood-sugar levels of people with type 1 (insulin-dependent) diabetes.

This is the first type 1 diabetes treatment trial involving leptin, which is naturally produced by fat cells and involved in body-weight regulation. For this study, UT Southwestern researchers will be using metreleptin, a slightly modified form of the hormone that has been well-tolerated in other clinical trials.

"Leptin has been very effective in improving diabetes in patients with lipodystrophies who have extreme lack of body fat, and recently leptin therapy has helped improve blood sugar control in animal models of type 1 diabetes," said Dr. Abhimanyu Garg, professor of internal medicine and principal investigator of the trial. "Although we have no assurances that this will work in humans, we hope that the addition of leptin will be beneficial to patients with type 1 diabetes."

The phase 1 study also is designed to evaluate the safety and tolerability of adding leptin to a diabetes treatment regimen.

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. The autoimmune disease, for which there is no cure, affects about 1 million people in the U.S.

Insulin treatment has been the gold standard for type 1 diabetes since its discovery in 1922. The laboratory of Dr. Roger Unger, professor of internal medicine at UT Southwestern, previously found that insulin's benefit resulted from its suppression of glucagon, a hormone produced by the pancreas that raises blood-sugar levels in healthy individuals.

More recently, Dr. Unger's lab, using mouse models of type 1 diabetes, found that administering leptin instead of insulin resulted in better management of blood-sugar variability and lipogenesis, the conversion of simple sugars into fatty acids.

For the clinical study, 12 to 15 participants will add leptin twice a day to their standard insulin therapy over a five-month period. The trial will last a total of seven months and will include 11 visits – an initial screening, four inpatient visits and six outpatient evaluations – to UT Southwestern. The first inpatient visit will last a minimum of four days; the others will take two days each.

To be eligible for the initial screening, prospective trial participants must be between 18 and 50 years of age, have a body mass index (BMI) less than 25, and have been diagnosed with type 1 diabetes. BMI is a weight-to-height ratio commonly used in doctors' offices to gauge obesity. A normal BMI is between 18.5 and 25.

Dr. Gregory Clark, assistant professor of internal medicine and a trial investigator, said one incentive to take part in the trial is that participants might lose weight.

"Leptin is known to decrease appetite, so it's likely that participants won't be as hungry," he said. "We hope that the addition of leptin also

reduces the blood levels of cholesterol, which increase the risk of coronary heart disease, one of the long-term complications of diabetes."

Dr. Unger emphasized that the goal is not to find a replacement for insulin, but to obtain stable glucose levels, something that has eluded monotherapy with insulin. The theory is that adding leptin might allow a substantial reduction in insulin dose and lower the risk of low blood glucose levels.

"If it works in humans as well as it does in rodents, it will be a major step forward," said Dr. Unger. "In rodents, it eliminated the wide swings in glucose that occur with insulin alone and lowered indices of cholesterol formation. The hope is that it will improve both short- and long-term quality of life for patients with type 1 diabetes."

Provided by UT Southwestern Medical Center

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