

## Combination injection improves glucose control for patients with type 2 diabetes

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A multinational clinical trial led by UT Southwestern Medical Center and others found that injection of a new long-acting insulin combined with another drug improves glucose control in patients with Type 2 diabetes and, additionally, is associated with weight loss.

The trial compared <u>glucose control</u> of participants receiving daily injections of either basal insulin glargine or IDegLira, which is a mixture of insulin degludec and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist. Liraglutide stimulates cells in the pancreas to produce insulin. The study findings were published today in the *Journal of the American Medical Association*.

"Many patients who are on an oral agent and basal insulin are unfortunately not at goal glycemia. Treatment options for such patients are to either increase the basal insulin dose or to add additional shots of insulin at mealtimes. The downside of both of these approaches is weight gain and hypoglycemia (low blood sugar)," said the study's lead author, Dr. Ildiko Lingvay, Associate Professor of Internal Medicine and Clinical Sciences at UT Southwestern. In addition, taking multiple injections per day also increases the burden on the patient.

Currently, about two-third of patients with Type 2 diabetes who are treated with basal insulin are not in good glucose control, Dr. Lingvay said.

"The clinical trial found that participants treated with the combination



product had more improvement in their HbA1C (hemoglobin A1C) test than those treated with basal insulin alone, they had <u>weight loss</u> rather than weight gain, and they had many fewer episodes of hypoglycemia," she added.

The phase 3 trial, conducted from September 2013 to November 2014, enrolled 557 participants with uncontrolled Type 2 diabetes in 75 treatment centers located in 10 countries. At the time they enrolled, study participants were taking an oral diabetes medication, metformin, as well as basal insulin glargine. All remained on the oral medication.

Participants were then randomly assigned to continue on insulin glargine - or to switch to daily injections of IDegLira. Those who were assigned to the insulin glargine group had their insulin dose sequentially increased as high as necessary to bring their glucose levels under control. For those taking IDegLira, dosage was also increased based on glucose readings, but there was a cap on the amount their dosage could be increased because of limits on liraglutide dosage.

Participants who took the combination product saw their glucose levels drop faster. On average, the HbA1C blood sugar level for participants on IDegLira dropped from 8.4 to 6.6. On average, the HbA1C level for participants on <u>insulin glargine</u> dropped from 8.2 to 7.1. The HbA1C test indicates the average blood glucose level over a three-month period; participants with an HbA1C level below 7 are considered within normal range.

Those taking IDegLira lost an average of about 3 pounds compared with an average weight gain of nearly 4 pounds for the glargine group. Only 6.1 percent of <u>participants</u> on the combination product experienced confirmed episodes of nighttime hypoglycemia compared with 24.4 percent of the patients on the basal glargine.



"The advantage of the combination product is that the treatment burden is the same as taking a <u>basal insulin</u> - one shot a day - but you are getting an additional product that works through a different mechanism and addresses different pathophysiologic defects of the disease. The liraglutide affects satiety and induces weight loss, while also stimulating <u>insulin secretion</u>. The combination product addresses more underlying abnormalities present in this disease," said Dr. Lingvay.

Insulin degludec, which was approved last fall by the Food and Drug Administration, is the longest-acting insulin currently available.

"Patients on IDegLira did better overall, especially when factoring in weight loss and decreased hypoglycemia risk," said Dr. John Buse, Professor of Medicine at the University of North Carolina School of Medicine and senior author on the study.

## Provided by UT Southwestern Medical Center

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