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Researchers at UT Southwestern launch study for head-to-head comparison of widely used diabetes drugs

DALLAS – June 3, 2013 – UT Southwestern Medical Center researchers are seeking 150 adults with type 2 diabetes to take part in the local arm of a major national clinical trial that will compare benefits and side effects of four widely used therapies to lower blood-sugar levels.

Diabetes specialists at UT Southwestern and at 36 other sites across the country are testing the four medications, which will be used in combination with metformin, the most common first-line diabetes medication, to compare the long-range effect on lowering blood-sugar (glucose) levels, complications, and overall quality of life over a five-year span.

"We need to know which combination of medications works best and has fewer side effects so that we can recommend the best choice for our patients," said Dr. Philip Raskin, professor of internal medicine who will lead the UT Southwestern investigation. "Since these drugs are already widely in use, the best way to do that is a head-to-head comparison on a variety of factors."

The National Institutes of Health-funded study, called the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness (GRADE) study, launched today. Individuals interested in taking part at UT Southwestern can contact 214-DIABETES (214-342-2383) to see if they qualify for this or other diabetes-related trials.

Researchers are recruiting volunteers, age 30 and older, who have been diagnosed with type 2 diabetes within the past five years. Those who qualify may be on metformin, but not on any other diabetes medication. During the study, all trial participants selected will take metformin, along with a second medication randomly assigned. All medications are approved for use with metformin by the U.S. Food and Drug Administration. GRADE participants will have their diabetes medications provided free of charge and managed, including at least four medical visits per year. Other health care will be received through their own providers.

The four types of medications being tested are:

- Sulfonylurea, which increases insulin levels directly.
- A DPP-4 inhibitor, which indirectly raises insulin levels by increasing the effect of a naturally occurring intestinal hormone.

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- A GLP-1 agonist, which increases the amount of insulin released in response to nutrients.
- A long-acting insulin.

Diabetes is a chronic disease characterized by high blood-glucose levels. Uncontrolled diabetes may result in blindness, kidney damage, heart disease, stroke, and circulation problems resulting in amputations. In 2010, the latest figures available, nearly 10 percent of Texas adults, or about 1.8 million, reported having been diagnosed with diabetes. The prevalence of diabetes in Texas increased by 56.6 percent between 2000 and 2010, with the highest levels reported among African Americans, according to an April 2013 report by the Department of State Health Services.

GRADE (ClinicalTrials.gov number: NCT01794143) is supported under NIH grant U01DK098246. Additional support in the form of donation of supplies for GRADE comes from the National Diabetes Education Program, Sanofi-Aventis, Bristol-Myers Squibb, Novo Nordisk, Merck, BD Medical, and Roche Diagnostics.

Dr. Raskin is a member of UT Southwestern's division of endocrinology, which was recognized by *U.S. News & World Report* in its 2012-2013 "Best Hospitals" annual issue. He also has an appointment in the Touchstone Diabetes Center, which focuses on the basic science and clinical aspects of type 1 and type 2 diabetes, and on questions related to the impact of diabetes and obesity on cardiovascular disease outcome and cancer incidence. Others on the clinical trial's research team include Dr. Chanhaeng Rhee, assistant professor of internal medicine.

About UT Southwestern Medical Center

UT Southwestern, one of the premier academic medical centers in the nation, integrates pioneering biomedical research with exceptional clinical care and education. The institution's faculty has many distinguished members, including five who have been awarded Nobel Prizes since 1985. Numbering more than 2,700, the faculty is responsible for groundbreaking medical advances and is committed to translating science-driven research quickly to new clinical treatments. UT Southwestern physicians provide medical care in 40 specialties to nearly 90,000 hospitalized patients and oversee more than 1.9 million outpatient visits a year.

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