

CLINICAL RESEARCH

Current clinical research related to the health of ethnic minority populations is essential to eliminate health disparities. Readers of *Ethnicity & Disease* may be interested in the progress and results of the following clinical trials. These trials describe only some of the research performed in ethnic minority health; other current trials may be found at www.clinicaltrials.gov. The information below was accurate at press time; the study researchers should be contacted for more information.

TARGETING INFLAMMATION USING SALSALATE FOR TYPE 2 DIABETES—STAGE II (TINSAL-T2D-II)

Growing evidence over recent years supports a potential role for low-grade chronic inflammation in the pathogenesis of insulin resistance and type 2 diabetes. In this study, we will determine whether salsalate, a member of the commonly used nonsteroidal anti-inflammatory drug class, is effective in lowering blood glucose in patients with type 2 diabetes. The study will determine whether salicylates represent a new pharmacologic option for diabetes management. The

study is conducted in 2 stages. Enrollment in the first stage is complete. The primary objective of the first stage was to select a dose of salsalate that is both well-tolerated and demonstrates a trend toward improvement in glycemic control. The primary objective of stage II of the study is to evaluate the effects of salsalate on blood sugar control in diabetes, the tolerability of salsalate use in patients with type 2 diabetes, and the effects of salsalate on measures of inflammation, the

metabolic syndrome, and cardiac risk.

Inclusion criteria: age 18–75 years; type 2 diabetes on diet and exercise therapy or monotherapy with metformin, insulin secretagogue, α -glucosidase inhibitors, or bile acid sequestrants; fasting plasma glucose ≤ 225 mg/dL and hemoglobin A1C $\geq 7\%$ and $\leq 9.5\%$ at screening.

Exclusion criteria: prior participation in stage I of TINSAL-T2D; type 1 diabetes or history of ketoacidosis; history of severe

diabetic neuropathy; history of long-term therapy with insulin (>30 days) within the last year; therapy with rosiglitazone, pioglitazone, or exenatide; pregnancy or lactation.

Study start: November 2008
Study end: October 2011

This study is currently recruiting patients. Contact Allison B. Goldfine, MD, Joslin Diabetes Center; 617-732-2643; allison.goldfine@joslin.harvard.edu.

Sponsored by: the Joslin Diabetes Center and the National Institute of Diabetes and Digestive and Kidney Diseases

ORAL INSULIN FOR PREVENTION OF DIABETES IN RELATIVES AT RISK FOR TYPE 1 DIABETES MELLITUS

Prior research has shown that oral insulin may delay or prevent type 1 diabetes in participants with high levels of antibodies that are directed against insulin itself (mIAA). This study will randomize eligible participants to receive either oral insulin (7.5 mg of recombinant human insulin crystals) or placebo daily. All participants will be seen at a study site for a follow-up evaluation 3 and 6 months after randomization and every 6 months thereafter.

Participants will be contacted by phone between visits to assess changes in diabetes status, medication compliance, and adverse events. Participants will be followed until development of type 1 diabetes or the conclusion of the study. The trial is expected to last 7–8 years or until the required amount of information is gathered.

Inclusion criteria: age 3–45 years, have a relative who was diagnosed with type 1 diabetes

before age 40 and started on insulin therapy within 1 year of diagnosis.

Exclusion criteria: mIAA-positive but no other autoantibodies, severe active disease (eg, chronic active hepatitis, severe cardiac, pulmonary, renal, hepatic, immune deficiency or disease that is likely to limit life expectancy), prior participation in a trial for prevention of type 1 diabetes, history of treatment with insulin or oral hypoglycemic agent, history of therapy with immunosup-

pressive drugs or glucocorticoids in the past 2 years for a period >3 months, ongoing use of medications known to influence glucose, pregnancy or intention to become pregnant while on study.

Study start: February 2007
Study end: February 2014

This study is currently recruiting patients. Contact Jeff Krischer, PhD, principal investigator, University of South Florida.

Sponsored by: the National Institute of Diabetes and Digestive and Kidney Diseases, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institute of Allergy and Infectious Diseases, National Center for Research Resources, American Diabetes Association, and Juvenile Diabetes Research Foundation

DIABETES CONNECTED HEALTH STUDY

Sponsored by: Massachusetts General Hospital

This trial will examine the effect of the Diabetes Connected Health Tool, which is a secure website shared between diabetes patients and their providers and displays blood glucose values in graphical format. We hypothesize that the Diabetes Connected Health Tool will result in overall better Diabetes Care, in terms of better blood glucose control, improved patient-provider interaction, and better patient satisfaction towards their care.

Patients enrolled into the intervention arm will use a

glucometer that will upload the blood glucose readings to a secure, web-based portal where they can view a detailed graphical representation of their blood glucose levels over time, read educational material regarding diabetes management, and receive personalized tips and feedback from their physicians (who will also have access to their patients' information on the web portal and contact them by an embedded messaging system). Patients with new high or low readings will be flagged. Provid-

ers can initiate messages regarding symptoms or medications. A medication summary and log of all readings uploaded with date and time will be displayed on the website and will require the patient to enter comments regarding each critical reading.

Inclusion criteria: age ≥ 18 years, diagnosis of type 2 diabetes, able to speak and read English, hemoglobin A1C $> 7.5\%$ in the last 12 months, currently self-monitoring blood glucose, access to the internet for the 6 months the study will run.

Exclusion criteria: cognitive or physical impairments that preclude using a glucometer or computer.

Study start: January 2009

Study end: June 2010

This study is not yet recruiting patients. Contact Ellen E. Murchver, MSW, Partners Health-Care, Boston, Massachusetts; 617-643-0272; emurchver@partners.org.

EMORY LATINO DIABETES EDUCATION PROGRAM

Sponsored by: Emory University, Sanofi-Aventis, Eli Lilly and Company, Takeda Global Research & Development Center, Inc, and Novo Nordisk

Latinos represent the largest minority group in the United States, with a population of 35 million or 12.5%. National surveys indicate that the prevalence of type 2 diabetes is 1.9 times higher in Latinos than non-Whites, and $\approx 24\%$ of Latinos aged > 45 years have diabetes. In Georgia, Latinos make up $\approx 6.5\%$ of the population. From 1990 to 2000, the prevalence of diabetes in Fulton and Dekalb Counties, 2 of the most populated areas in Georgia and the Atlanta metropolitan area, increased by 30%. Language and cultural barriers are the 2 most important obstacles

in educating and improving the care of Latino patients with diabetes. Less than 5% of physicians, 2% of nurses, and 2.5% of dentists in the United States speak Spanish.

The Emory Latino Diabetes Education Program has been in existence since December 2005. Our program aims to deliver diabetes education in Spanish to the under-served Latino community in Metro Atlanta. Program participants attend an initial 2.5-hour diabetes education class in Spanish. The class curriculum follows the American Association of Diabetes Educators 7 self-care behaviors: healthy eating, being

active, monitoring, medication use, problem-solving, and healthy coping. Participants are invited to return to a follow-up session within 6 months. Follow-up sessions are held in the late afternoon. These sessions are discussion-based and include an activity such as salsa lessons and cooking demonstrations.

Participants complete a questionnaire that assesses behaviors and social and demographic characteristics of the Latino community. In order to track patient outcomes, at the beginning of each class their hemoglobin A1C, blood pressure, weight, body mass index, and

waist circumference are measured.

Inclusion criteria: age ≥ 18 years, diagnosis of type 2 diabetes, Spanish speaking.

Exclusion criteria: age < 18 years.

Study start: October 2008

Study end: December 2011

This study is currently recruiting patients. Contact Amparo Gonzalez, RN, Emory University School of Medicine, Atlanta, Georgia; 404-778-1697; amparo.gonzalez@emory.edu.