Open Clinical Trials for Native Americans With Diabetes Mellitus

Providing access to clinical trials for patients with diabetes mellitus can be a challenge, but a significant number of trials are now recruiting patients. The clinical trials listed below are all open as of October 31, 2019; and are focused on diabetes mellitus-related treatments for American Indians. For additional information and full inclusion/exclusion criteria, please consult clinicaltrials.gov.

Cross-Sectional and Longitudinal Studies of "Pre-Diabetes" in the Pima Indians

The Pima Indians of Arizona have the highest prevalence and incidence of type 2 diabetes of any population in the world. Prospective analyses in this population have identified insulin resistance and a defect in early insulin secretion as risk factors for the development of the disease. To identify the genetic and environmental determinants of diabetes we plan to study Pima Indian families to determine: (1) if there are genes that segregate with metabolic risk factors for diabetes which might therefore be genetic markers for type 2 diabetes; and (2) the mechanisms mediating genetic and environmental determinants of insulin resistance and impaired insulin secretion.

ID: NCT00340132
Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Contact: Clifton Bogardus, MD, cbogardus@phx.niddk.nih.gov
Location: NIDDK, Phoenix, AZ

Empaglifozin in Early Diabetic Kidney Disease

Diabetes is common among American Indian people and diabetic kidney disease is a common complication. Kidney disease caused by diabetes can lead to the need for kidney replacement, by dialysis or kidney transplant, and is also associated with higher risk of early death. A new diabetes medicine called empagliflozin may slow kidney disease from type 2 diabetes. Researchers want to learn if it protects the kidneys when used in very early stages of diabetic kidney disease.

ID: NCT03173963
Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Contact: Helen C Looker, helen.looker@nih.gov
Location: NIDDK, Phoenix, AZ

Family Investigation of Nephropathy and Diabetes

The Family Investigation of Nephropathy and Diabetes (FIND) is a multicenter study designed to identify genetic determinants of diabetic kidney disease. FIND will be conducted in 11 centers and in many ethnic groups throughout the United States. Two different strategies will be used to localize genes predisposing to kidney disease: a family-based genetic linkage study and a case-control study that utilizes admixture linkage disequilibrium. The center will conduct family-based linkage studies among American Indian populations in the southwestern United States.

ID: NCT00342927
Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Contact: William C Knowler, MD, wknowler@phx.niddk.nih.gov
Location: NIDDK, Phoenix, AZ

Look AHEAD: Action for Health in Diabetes

The Look AHEAD study is a multi-center, randomized clinical trial to examine the long-term effects of a lifestyle intervention designed to achieve and maintain weight loss. The study will investigate the effects of the intervention on heart attacks, stroke and cardiovascular-related death in individuals with type 2 diabetes who are also overweight or obese.

ID: NCT00017953
Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Location: Southwestern American Indian Center, Phoenix, AZ

Vitamin D and Type 2 Diabetes Study

The goal of the Vitamin D and type 2 diabetes (D2d) study is to determine if vitamin D supplementation works to delay the onset of type 2 diabetes in people at risk for the disease and to gain a better understand how vitamin D affects glucose (sugar) metabolism.

ID: NCT01942694
Sponsor: Tufts Medical Center
Locations: Southwest American Indian Center; Phoenix, AZ; Orlando VA Medical Center, FL; Atlanta VA Medical Center, Decatur, GA; Omaha VA Medical Center, NE

Reducing Diabetes Risk Factors in American Indian Children: Tribal Turning Point (TTP)

This study will evaluate a behavioral intervention designed to reduce risk factors for type 2 diabetes in American Indian youth aged 7-10 years.

ID: NCT03573856
Sponsor: University of Colorado, Denver
Contact: Katherine Sauder, PhD,

katherine.sauder@ucdenver.edu;
Dana Dabelea, MD, PhD, dana.dabelea@ucdenver.edu
Location: Childrens Hospital Colorado, Aurora

Strong Men, Strong Communities Diabetes Risk Reduction in American Indian Men (SMSC)

SMSC will inform the design and implementation of culturally informed, community-based lifestyle interventions for diabetes prevention in AI men in our partner communities and elsewhere, as well as in men of other minority groups who experience a heavy burden of diabetes.
ID: NCT02953977
Sponsor: Washington State University
Contact: Kaimi Sinclair, PhD, MPH, kaimi.sinclair@wsu.edu
Location: IREACH, Seattle, WA

Growing Resilience in Wind River Indian Reservation (GR)

The Growing Resilience research leverages reservation-based assets of land, family, culture, and front-line tribal health organizations to develop and evaluate home food gardens as a family-based health promotion intervention to reduce disparities suffered by Native Americans in nearly every measure of health. Home gardening interventions show great promise for enabling families to improve their health, and this study aims to fulfill that promise with university and Wind River Indian Reservation partners. The investigators will develop an empowering, scalable, and sustainable family-based health promotion intervention with, by, and for Native American families and conduct the first randomized controlled trial to assess the health impacts of home gardens.
ID: NCT02672748
Sponsor: University of Wyoming
Location: University of Wyoming, Laramie

A Comparative Effectiveness Study of Major Glycemia-lowering Medications for Treatment of Type 2 Diabetes (GRADE)

The GRADE Study is a pragmatic, unmasked clinical trial that will compare commonly used diabetes medications, when combined with metformin, on glycemia-lowering effectiveness and patient-centered outcomes.
ID: NCT01794143
Sponsor: GRADE Study Group
Location: Southwestern American Indian Center, Phoenix, AZ

Home-Based Kidney Care in Native Americans of New Mexico (HBKC)

New Mexico American Indians are experiencing an epidemic of chronic kidney disease due primarily to the high rates of obesity and diabetes. The present study entitled Home-Based Kidney Care is designed to delay / reduce rates of end stage renal disease by early interventions in chronic kidney disease (CKD). Investigators propose to assess the safety and efficacy of conducting a full-scale study to determine if home based care delivered by a collaborative team composed of community health workers, the Albuquerque Area Indian Health Board and University of New Mexico faculty will decrease the risk for the development and the progression of CKD.
ID: NCT03179085
Sponsor: University of New Mexico
Contact: Vallabh Shah, PhD, vshah@salud.unm.edu;
Kevin English, PhD, kenglish@aaihb.org
Location: University of New Mexico, Albuquerque

Home-based Prediabetes Care in Acoma Pueblo - Study 1

Our major goal of implementing educational interventions to slow the current rate of increase in diabetes in Native communities is aligned with the National Institute of Health (NIGMS) and New Mexico INBRE's vision in reducing health disparity using innovative interventions. The investigators propose following aims: (1) Recruit and Screen 300 community members in Acoma Pueblo, New Mexico to identify incident cases of pre-diabetes for the proposed study of Home Based Diabetes Care (HBDC); (2) Enroll 150 Acoma Natives aged 21-70 years, at risk for type 2 diabetes mellitus and conduct HBDC for a 16-week lifestyle intervention in a longitudinal cohort study.
ID: NCT04029298
Sponsor: University of New Mexico
Contact: Matthew Bouchonville, MD,
mbouchonville@salud.unm.edu;
Vallabh Shah, PhD, vshah@salud.unm.edu