

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.

ALISKIREN TRIAL IN TYPE 2 DIABETES USING CARDIOVASCULAR AND RENAL DISEASE ENDPOINTS (ALTIITUDE)

Sponsored by: Novartis

The purpose of this study is to determine whether, in patients with type 2 diabetes and preexisting disease of the heart and the circulatory system or the kidney, aliskiren at a target dose of 300 mg once daily (compared to placebo), on top of conventional treatment, reduces death and disease caused by the heart,

the circulatory system, and the kidney.

Inclusion criteria: age ≥ 35 years, type 2 diabetes and at least one of the following: microalbuminuria, microalbuminuria and reduced kidney function, previous heart attack and reduced kidney function, previous stroke and reduced kidney function,

heart failure and reduced kidney function, coronary artery disease and reduced kidney function.

Exclusion criteria: type 1 diabetes, cardiovascular event or procedure ≤ 3 months before visit 1, unstable serum creatinine, baseline serum potassium > 5.0 mmol/L, treatment with 2 renin-angiotensin-aldosterone

system blockers, class III or IV heart failure, renal artery stenosis.

Study start: October 2007

Study end: January 2012

This study is currently recruiting participants. Contact Novartis, 862-778-8300.

A STUDY TO ASSESS THE EFFICACY AND SAFETY OF ENTERIC-COATED ACETYLSALICYLIC ACID IN PATIENTS AT MODERATE RISK OF CARDIOVASCULAR DISEASE

Sponsored by: Bayer

The use of acetylsalicylic acid in the primary prevention of cardiovascular events has been extensively studied. However, the overall risk level of the study populations was low ($< 10\%$ 10-year). The current study is designed to prove the efficacy and tolerability of 100 mg enteric-coated aspirin versus placebo in the prevention of cardiovascular disease (CVD) events, which include fatal and nonfatal myocardial infarction, fatal and nonfatal stroke, and cardiovascular death, in a population with no history of known CVD who are at mod-

erate risk (20%–30% 10-year) of CVD. Participants are treated in a standard care setting and may be treated for underlying risk factors as defined by the treating physician. Outcome events will be adjudicated by an endpoint adjudication committee, and the study will be monitored by an independent data safety monitoring board.

Inclusion criteria: age ≥ 50 years (men) or ≥ 60 years (women); 2 or 3 of the following risk factors: elevated cholesterol, low high-density lipoprotein cholesterol, smoking, elevated blood

pressure, current use of blood pressure medication, and positive family history of early coronary heart disease.

Exclusion criteria: clinical history of CVD, myocardial infarction, stroke, coronary artery angioplasty or stenting, coronary artery bypass graft, relevant arrhythmias, or congestive heart failure; higher than moderate risk on the basis of their diabetes status, other factors known to the investigator, or the currently used national risk score; contraindications to the study drug, eg, hypersensitivity to acetylsalicylic acid, increased

risk of bleeding or gastric or duodenal ulcer, or diagnosed reflux esophagitis; any medical condition or psychiatric or substance abuse disorder that, in the opinion of the investigator, is likely to affect the patient's ability to complete the study or precludes the patient's participation in the study.

Study start: July 2007

Study end: January 2014

This study is currently recruiting participants. Contact Bayer Clinical Trials, clinical-trials-contact@bayerhealthcare.com.

CLINICAL RESEARCH

RENAL INSUFFICIENCY AND CARDIOVASCULAR EVENTS (RIACE)

Reduced glomerular filtration rate (GFR) is a powerful predictor of cardiovascular morbidity and mortality in the general population, independent of traditional cardiovascular risk factors. Since type 2 diabetes patients show increased cardiovascular morbidity and mortality compared with the general population, identifying predictors of cardiovascular disease in these patients is of fundamental importance for clinical purposes.

One of these predictors is increased urinary albumin excretion rate, which is associated with an increased risk of cardiovascular disease more than of end-stage renal disease. However, a growing body of evidence indicates that a significant proportion of normoalbuminuric diabetic patients, particularly with type 2 diabetes, may exhibit reduced GFR. The predictive role of this abnormality toward cardiovascular events

and death, independent of albuminuria and other known risk factors, in the diabetic population is unknown. This observational study will assess the association of reduced estimated GFR with cardiovascular morbidity and mortality in a large Italian population ($\geq 15,000$ participants) of type 2 diabetes outpatients during a 4-year follow-up.

Inclusion criteria: age 40–80 years, type 2 diabetes.

Sponsored by: the Diabetic Nephropathy Study Group, Italian Society of Diabetology

Exclusion criteria: dialysis or renal transplantation.

Study start: June 2008.

Study end: September 2012.

This study is currently recruiting participants. Contact Giuseppe Pugliese, MD, PhD, Sant'Andrea Hospital, Division of Diabetology, Rome, Italy 00189; 39-063377 x 5049; giuseppe.pugliese@uniroma1.it.