

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 exciting 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.

THE ROLE OF ENDOTHELIUM DYSFUNCTION IN PROGRESSION OF CHRONIC KIDNEY DISEASE AFTER ACUTE KIDNEY INJURY

Sponsored by: the University of Alabama at Birmingham

This is an observational natural-history study, the goal of which is to understand how acute kidney injury leads to chronic kidney disease so therapies can be found to alter the progression of events, improving the long-term outcomes of children who develop acute kidney injury.

Inclusion criteria: age 5–20 years, decrease in renal function by $\geq 25\%$, renal function has returned to normal.

Exclusion criteria: history of chronic disease, cancer, congenital heart disease, organ transplantation, liver disease, pulmonary disease, diabetes or other

primary metabolic condition, severe neurologic impairments, hypertension, infectious disease or renal disease, smoker, renal disease with primary cause (hemolytic uremic syndrome, glomerulonephritis).

Study end: July 2008

This study is recruiting patients. Contact Michelle Sharbono, Birmingham, Alabama; phone: 205-558-2792; michelle.sharbono@chsys.org.

Study start: July 2006

HALT PROGRESSION OF POLYCYSTIC KIDNEY DISEASE (HALT PKD)

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

The efficacy of interrupting the renin-angiotensin-aldosterone system (RAAS) on the progression of cystic disease and on the decline in renal function in autosomal dominant kidney disease will be assessed in two multicenter randomized clinical trials that will target different levels of kidney function: 1) early disease defined by glomerular filtration rate (GFR) > 60 mL/min/1.73 m² (study A); and 2) moderately advanced disease defined by GFR 30–60 mL/min/1.73 m² (study B). Participants will be recruited and enrolled, either to study A or B, over the first two years. Partici-

pants enrolled in study A will be followed for a total of four years, while those enrolled in study B will be followed for four to six years. The two concurrent randomized clinical trials differ by eligibility criteria, interventions and outcomes to be studied.

Study A will examine the efficacy of angiotensin-converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) combination therapy as compared to ACEI monotherapy and usual vs low blood pressure targets on the percentage change in kidney volume in participants with preserved renal

function and high-normal blood pressure or hypertension ($> 130/80$ mm Hg). Study B will examine the effects of ACEI/ARB combination therapy as compared to ACEI monotherapy in the setting of standard blood pressure control (systolic blood pressure 120–130 mm Hg and diastolic blood pressure 70–80 mm Hg) on the time to a 50% reduction of baseline estimated GFR, end-stage renal disease, or death in hypertensive individuals with moderate renal insufficiency.

Inclusion criteria: diagnosis of autosomal dominant polycystic kidney disease, age 15–49 years

(study A) or 18–64 years (study B), GFR > 60 mL/min/1.73 m² (study A) or GFR 30–60 mL/min/1.73 m² (study B), blood pressure $\geq 130/80$ mm Hg or receiving treatment for hypertension, informed consent.

Exclusion criteria: contact investigators for exclusion criteria.

Study start: January 2006

Study end: December 2011

This study is recruiting patients. Contact Robin Woltman; phone: 314-362-1318; robinw@wubios.wustl.edu.

RENAL TRANSPLANTATION AND INHALED ANESTHETIC SEVOFLURANE (SEVOREIN)

Sponsored by: University Hospital, Bordeaux

Renal transplantation is characterized by ischemia-reperfusion lesions in allograft. Sevoflurane reduces glomerular lesions in kidneys of patients undergoing cardiovascular surgery and presenting with ischemia-reperfusion phenomena. The purpose of this study is to evaluate the effects of sevoflurane on the recovery of renal graft function in patients after kidney transplantation. This study will be a randomized, double-blind,

controlled clinical trial; 120 patients undergoing renal allograft transplantation will be included.

Patients will be divided into two groups: one group of patients will receive sevoflurane (evaluated treatment) for anesthesia and the other will receive propofol (reference treatment). We will evaluate renal function for one year after transplantation. Our results will confirm whether sevoflurane protects

kidney function from ischemia-reperfusion lesions.

Inclusion criteria: age ≥ 18 years, scheduled to undergo renal allograft transplantation, transplant under cold ischemia duration >20 hours or donor age >50 years or donor cardiac arrest, informed consent.

Exclusion criteria: halogenated anesthetic agent hypersensitivity, medical history or family history of malignant hyperthermia, porphyria, pregnancy or

breast feeding, hyperimmunized patient, participation in an immunosuppressive drug trial.

This study is not yet open for patient recruitment. Contact Francois Sztark, Département d'Anesthésie Réanimation, 1 Hôpital Pellegrin, CHU de Bordeaux, Bordeaux 33076, France; phone: 33-5-56795514; francois.sztark@chu-bordeaux.fr.

THE CANADIAN PREVENTION OF RENAL AND CARDIOVASCULAR ENDPOINTS TRIAL

Sponsored by: Memorial University of Newfoundland

Advanced kidney disease with its associated heart and blood vessel problems is becoming more frequent. These problems markedly affect length and quality of life and are expensive to treat. Treatments can prevent development of advanced kidney and heart disease, but these treatments are not being optimally applied in the current health system. This study aims to identify people with relatively early-stage chronic kidney disease (CKD). With the participation of these people, the study will test whether a nurse-coordinated clinic that employs a medical kidney specialist will be more effective than usual care in reducing or delaying the onset

of advanced kidney disease and heart and blood vessel problems such as heart attack, stroke, and death. The study will also address issues of costs associated with care and illness. The nature of the care provided by health-care professionals will be studied to see how best to achieve good health outcomes.

Inclusion criteria: age 40–75 years, diabetes mellitus (by clinical history with documented plasma glucose levels in the diabetic range or on hypoglycemic medications) and CKD as documented by calculated (Cockcroft-Gault equation) creatinine clearance $25-60$ mL/min/ 1.73 m² OR nondiabetic with CKD and proteinuria >1 g/L

by dipstick in random urine at screening OR nondiabetic with CKD but without proteinuria.

Exclusion criteria: unwillingness to provide informed consent, likely to die of any known existing disease within six months, recently unstable/advanced cardiovascular disease (myocardial infarction or acute coronary syndrome, hospitalized heart failure, transient ischemic attack or stroke, leg amputation or gangrene in past six months), currently receiving active treatment for a malignant, neoplastic disease other than localized non-melanoma skin cancer, progressive kidney disease currently treated by immunotherapy, currently receiving dialysis or likely to do so

within six months, current organ transplant recipient or planned within six months, currently receiving ongoing care for CKD or cardiovascular disease in a multiple intervention disease management program, currently enrolled in another interventional trial, residing in a location not amenable to followup for the trial.

Study start: April 2005
Study end: December 2008

This study is recruiting patients. Contact Brendan J. Barrett, MD, Memorial University of Newfoundland, St. John's, Newfoundland and Labrador, A1B 3V6, Canada; phone: 709-777-8073; bbarrett@mun.ca.