

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 EFFECT OF DIET AND EXERCISE IN HEART FAILURE

Sponsored by: Baylor College of Medicine and the National Institutes of Health

A growing number of people in this country are overweight or obese, which is concerning because increasing weight has been shown to increase the risk of developing heart failure. People who are obese commonly have other diseases, such as high blood pressure, high cholesterol, and diabetes, which increase the risk of developing heart disease.

“Lifestyle intervention programs” are programs that help people lose weight by changing their eating habits and exercise/activity routines. Weight loss and exercise lower the risk of developing diabetes and improve diabetes control, improve cho-

lesterol abnormalities, and lower blood pressure. These programs have not previously included heart failure patients, however.

We hypothesize that using a lifestyle intervention program in addition to the usual medications for heart failure will result in improved symptoms of heart failure and control of the metabolic syndrome. This study will be the first research study to look at the use of diet and exercise to treat heart failure patients who are overweight/obese and have the metabolic syndrome. From this study, we hope to learn whether diet and exercise are helpful in treating heart failure patients who are overweight.

Specifically, the study will look at the short-term effects on cardiac risk factors (blood pressure, cholesterol, blood sugar), heart failure symptoms, and exercise capacity.

Inclusion criteria: age 18–75 years, meet three or more of the National Cholesterol Education Program criteria for metabolic syndrome, must have New York Heart Association (NYHA) class II or III symptoms, body mass index ≥ 25 kg/m², VO₂ or exercise stress test within the last six months to exclude active ischemia or exercise-induced dysrhythmia.

Exclusion criteria: NYHA IV symptoms or six-minute walk

test < 300 m, blood pressure $> 160/100$ mmHg, active titration of cardiac medications, comorbid illness that limits expected lifespan or affect the safety of interventions, weight loss > 10 pounds of non-edematous body weight within the past three months, pregnancy, HIV, active tuberculosis, hepatitis C, cancer requiring treatment in the past 5 years.

Study start: March 2005

This study is recruiting patients. Contact Melissa Brock, RN, Ben Taub General Hospital, Houston, TX 77030, USA; phone 713-873-8772.

HEART FAILURE EVALUATION ACUTE REFERRAL TEAM TRIAL (HEARTT)

Sponsored by: the University of Alberta

Heart failure (HF) causes a substantial number of illnesses and deaths in Canada. In contrast to coronary heart disease, the mortality rate attributed to HF has decreased minimally, by only 14% in the last 35 years, despite a plethora of new therapeutic modalities that are proven to decrease mortality in HF. HF is also one of the leading causes

of hospitalizations; it accounts for the second highest total number of hospital days and the third highest number of patients affected. Approximately 20%–50% of HF patients will be readmitted to hospital with one year. Patients seen in the emergency department (ED) and discharged home from the ED are also at high risk for

readmissions. A local study by our group indicated that 44% of patients seen for HF in the ED have a 50% higher readmission rate at 30 days than do those admitted to hospital. This difference could be explained by a “care gap,” as evidenced by a low utilization of both angiotensin-converting enzyme inhibitors and beta-blockers in this

group. However, a lack of patient education on self-care and followup after ED discharge could also attribute to these rates. We will test an intervention that uses a multidisciplinary team to facilitate followup, provide HF education, and improve utilization of proven drug therapy in patients discharged with HF from the ED.

CLINICAL RESEARCH

The study will use an unblinded randomized controlled trial design. Eligible patients will include those discharged from the ED with a diagnosis of heart failure. All patients referred from the ED will be seen in a rapid referral clinic within one week. Eligible patients will then be randomized to an intervention arm or usual care. The usual care group will have a consultation letter with recommendations sent their family doctor and will

receive a booklet on HF. The intervention arm will be followed in clinic monthly by the multidisciplinary team. Medication will be initiated and titrated to target dose. Patients will receive education regarding HF, medications, lifestyle, diet, and self-management. Communication with the patient's primary care provider will also be enhanced.

Study start: August 2006

Study end: October 2008

Inclusion criteria: age ≥ 18 years, patients presenting to the ED with signs and symptoms of HF with a plan to discharge home.

Exclusion criteria: planned followup with cardiology or internal medicine after discharge from ED, heart transplant candidate or recipient, current Heart Function Clinic patient, left ventricular ejection

fraction >0.40 , unable or unwilling to attend clinic visits, HF that requires admission to hospital, living outside the Capital Health catchment area, participation in another HF clinical trial.

This study is not yet open for patient recruitment. Contact Ross T. Tsuyuki, University of Alberta, Edmonton, Alberta, Canada; phone: 780-492-8526; ross.tsuyuki@ualberta.ca

PROTECT-1: A STUDY OF THE SELECTIVE A1 ADENOSINE RECEPTOR ANTAGONIST KW-3902 TO ASSESS TREATMENT EFFECT ON HEART FAILURE AND RENAL FUNCTION

Loop diuretics are generally first-line therapy in patients hospitalized with acute heart failure syndrome (AHFS). Their use far exceeds that of vasoactive agents. Tubuloglomerular feedback (TGF) is the body's compensatory response to avoid excess fluid loss, and it is activated when elevated sodium concentrations in the distal tubule are detected. TGF is proposed as a contributing factor for the observed diuretic resistance that occurs in patients with heart failure. Higher doses of diuretics are required to overcome the decreased natriuresis and reduced renal blood flow induced by TGF. Ultimately, this action creates a vicious cycle of worsening renal function and diminished diuretic effectiveness.

The primary pharmacologic rationale for the use of KW-3902 in subjects with AHFS is its mechanism of action as an

adenosine A1 receptor antagonist. TGF promotes release of adenosine, and adenosine binding to A1 receptors causes vasoconstriction of the afferent arteriole, decreased renal blood flow, and enhanced sodium reabsorption by the proximal tubule. This action results in a decrease in glomerular filtration rate, diminished renal function, and sodium and water retention. Blocking adenosine A1 receptors via a selective adenosine receptor antagonist may limit sodium reabsorption by the proximal tubules without triggering TGF. It promotes vasodilation of the afferent arteriole of the glomerulus, and thus, this strategy offers the potential to overcome diuretic resistance or enhance diuretic responsiveness. It may also reduce the need for increasing diuretic doses that have been associated with worse outcomes.

The objectives of this study are to evaluate the effect of KW-3902 in addition to furosemide on heart failure signs and symptoms, renal function, and safety in subjects hospitalized with AHFS, volume overload, and renal impairment and to estimate and compare within-trial medical resource utilization and direct medical costs between patients treated with KW-3902 versus placebo.

Study start: August 2006

Inclusion criteria: age ≥ 18 years, oral loop diuretic prescribed as daily heart failure therapy prior to hospital admission, hospitalized for AHFS that requires IV diuretic therapy, impaired renal function.

Exclusion criteria: acute contrast-induced nephropathy; ongoing or planned IV therapy for heart failure with positive inotropic agents, vasopressors, vasodila-

tors, or mechanical support with the exception of IV nitrates; brain natriuretic peptide <250 pg/mL; ongoing or planned treatment with ultrafiltration, hemofiltration, or dialysis; severe pulmonary disease; significant stenotic valvular disease; heart transplant recipient or admitted for cardiac transplantation; clinical evidence of acute coronary syndrome in the two weeks prior to screening; heart failure due to significant arrhythmias; acute myocarditis or hypertrophic obstructive, restrictive, or constrictive cardiomyopathy; known hepatic impairment; noncardiac pulmonary edema, including suspected sepsis; allergy to soybean oil or eggs; history of seizure; stroke within 2 years.

This study is recruiting patients. Contact Howard C. Dittrich, NovaCardia, Inc., San Diego, CA 92130, USA; phone: 858-523-4505; hcd@novacardia.com.

Sponsored by: NovaCardia

**BETA-BLOCKER CONTINUATION VERSUS
INTERRUPTION IN HEART FAILURE WORSENING**

Sponsored by: Assistance Publique – Hôpitaux de Paris

The objective of the B-Convinced study is to demonstrate noninferiority of beta-blocker continuation compared to its interruption in patients with heart failure who are treated by a beta-blocker and present with an episode of heart failure wors-

ening with pulmonary edema that requires hospital admission.

Study start: November 2004

Study end: December 2007

Inclusion criteria: age ≥ 18 years, heart failure treated with

beta-blocker, hospitalization for heart failure worsening with pulmonary edema, left ventricular ejection fraction $< 40\%$.

Exclusion criteria: indication of intravenous positive inotropic treatment, indication to

withdraw beta-blocker treatment.

This study is recruiting patients. Contact Philippe Lechat, Hopital Pitie-Salpetriere, Paris, France; phone: 33-1-42-16-16-82; philippe.lechat@psl.ap-hop-paris.fr