

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.

STUDY OF THE ARACHIDONATE 5-LIPOXYGENASE ENZYME IN RISK FOR CORONARY HEART DISEASE

Sponsored by: the University of Florida

The focus of this study is to better understand why some adults develop heart disease and others do not. Many factors play a role in causing heart disease, such as diet and lifestyle. We also know that inflammation, a process in the body which causes painful joints in arthritis or swelling at a site of injury, also contributes to heart disease. In particular, we will address whether leukotrienes, a component of inflammation, are involved in promoting heart disease. We will study this by giving subjects at high risk for heart disease a drug called montelukast, which causes leukotrienes to have a reduced effect in the body. For comparison, we will give other subjects a placebo for the same amount of time. These subjects will then be crossed-over and will receive either montelukast or placebo

depending on which treatment they received first. We will compare these subjects by using blood tests to see if subjects who take montelukast show signs of less inflammation caused by early heart disease as compared to subjects who do not.

Inclusion criteria: age ≥ 18 years, current hypertension (blood pressure $>140/90$ mm Hg) or current use of antihypertensive medications, presence of one (and only one) additional risk factor for coronary heart disease as defined by the Adult Treatment Panel III guidelines (low density lipoprotein level 130–190 mg/dL, smoking, family history of heart disease, age >45 years for men or >55 years for women, Framingham score leading to 10-year risk of 10%–20%).

Exclusion criteria: current use of lipid-lowering medications;

current use of montelukast; poorly controlled hypertension (systolic blood pressure >160 mm Hg or diastolic blood pressure >100 mm Hg); use of steroid drugs, nonsteroidal anti-inflammatory drugs, or other anti-inflammatory medications in the two weeks prior to enrollment (low-dose aspirin (<325 mg) acceptable but indication must be cardiovascular); current recreational drug use; other cardiovascular disease or previous cardiovascular event; pregnancy or lactation; diabetes mellitus; lactose intolerance; contraindications to montelukast therapy; alcoholism; known hepatic disease; existing chronic obstructive pulmonary disease, asthma, allergic rhinitis, or other chronic immune, infectious, neoplastic, or inflammatory diseases; immunosuppressant ther-

apy or known immunosuppression due to disease; high-density lipoprotein cholesterol <40 mg/dL (although this would be a risk factor for heart disease, because of preliminary data that indicate that montelukast may lower HDL levels, we will exclude patients with abnormally low HDL from study); other criteria at investigator discretion that are deemed to make the subject a poor candidate for the study.

Study start: July 2006

Study end: July 2008

This study is currently recruiting patients. Contact Anzeela M Schentrup, PharmD, University of Florida Family Practice Medical Group Clinic, Gainesville, Florida; 352-273-6326; anzee@ufl.edu.

ESCAP: SUPERVISED EXERCISE FOR PATIENTS WITH CORONARY HEART DISEASE IN THE PRIMARY CARE SETTING

Sponsored by: Basque Health Service

In order to obtain the maximal health benefits, coronary heart disease (CHD) patients must attain an exercise intensity between 60% and 85% of the

maximal or symptom-limited heart rate. This intensity is not currently attained by the patients who are prescribed an unsupervised walking program. The ob-

jective of this randomized clinical trial is to investigate if CHD patients improve their functional capacity and quality of life more, and control their cardiovascular

risk factors better, by coming to their health centers to pedal for 30 minutes on a stationary bicycle three or more times a week. Patients will wear a heart rate

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monitor to ensure that they attain heart rates within the prescribed interval; they will be supervised by health personal, and the results will be compared with walking without supervision. For this purpose, low-risk CHD patients from 11 Spanish health centers will be randomly assigned to a supervised exercise group (ESCAP) or to another unsupervised walking group (control). Both groups will be provided with health education and the corresponding treatment for cardiovascular risk factor control

and complication prevention by their family physicians. The average changes observed in the two groups will be compared, on the basis of intention to treat through analysis of covariance. We will use mixed-effect models to take into account intra-patient and intra-center correlation.

Inclusion criteria: age 20–79 years, coronary heart disease low-risk patients.

Exclusion criteria: inclusion in cardiac rehabilitation programs, handicap for exercising, unstable angina, uncontrolled

atrial-ventricular arrhythmias, third-degree atrioventricular block (without pacemaker), uncompensated congestive heart failure, severe aortic stenosis, suspected or known dissecting aneurysm, active myocarditis or pericarditis, thrombophlebitis, recent embolism, acute systemic illness or fever, significant emotional distress (psychosis), orthostatic blood pressure drop of >20 mm Hg with symptoms, uncontrolled sinus tachycardia, resting ST segment displacement (>2 mm), uncontrolled diabetes

(resting blood glucose >400 mg/dL), other metabolic problems (eg, acute thyroiditis, hypokalemia or hyperkalemia, hypovolemia), resting blood pressure >200/110 mm Hg.

Study start: January 2005
Study end: December 2008

This study is currently recruiting patients. Contact Dr. Gonzalo Grandes, Primary Care Research Unit of Bizkaia, Bilbao, Bizkaia 48014, Spain; 34-94-600-66-38; gonzalo.grandes@osakidetza.net.

STUDY OF THE EFFICACY AND SAFETY OF TEZOSENTAN IN PATIENTS SCHEDULED FOR OPEN HEART SURGERY AND WITH PREOPERATIVE PULMONARY HYPERTENSION DUE TO LEFT HEART DISEASE

Sponsored by: Actelion

Endothelin-1 levels are increased during and after cardiac surgery with cardiopulmonary bypass and are associated with many deleterious consequences, including increased pulmonary arterial pressure (PAP), increased pulmonary vascular resistance (PVR), reduced myocardial contractility, and ultimately right ventricular failure. Right ventricular failure during weaning from cardiopulmonary bypass increases the risk of mortality and morbidity, especially in patients with elevated PAP before cardiac surgery. Endothelin-receptor antagonists have been shown to decrease PVR and PAP and improve right ventricular func-

tion in patients with pulmonary arterial hypertension. In animal models, endothelin-receptor antagonists decrease the incidence of post-bypass pulmonary hypertensive crises. The primary objective of this trial is to demonstrate that tezosentan, a dual endothelin-receptor antagonist, reduces the incidence of clinically relevant right ventricular failure in patients with preoperative pulmonary hypertension, due to left heart disease, undergoing cardiopulmonary bypass.

Inclusion criteria: age \geq 18 years, undergoing complex (surgery on two valves, on one valve and revascularization, or reoperation of a valve) cardiac

surgery on cardiopulmonary bypass with systolic PAP >40 mm Hg or mean PAP >30 mm Hg, undergoing cardiac surgery on cardiopulmonary bypass and having preoperative pulmonary hypertension due to left heart disease with systolic PAP >60 mm Hg, informed consent.

Exclusion criteria: systolic blood pressure <100 mm Hg; significant chronic lung disease; emergency surgery; pregnant/breast-feeding; investigational drug use within 28 days before randomization; complex adult congenital heart disease; severe concomitant illness limiting life expectancy to <6 months; par-

ticipation in a device study that will affect the outcome of the study; preoperative use of balloon pump, inotropes/vasopressors, or treatment for pulmonary arterial hypertension; known hypersensitivity to tezosentan or drugs of the same class or any of their excipients; severe liver impairment.

Study start: April 2007
Study end: March 2008

This study is currently recruiting patients. Contact Geraldine O'Riordan, RN, CCRN, Stanford, California; 650-498-6210; gor@stanford.edu.

A TRIAL OF INFLAMMATORY MARKERS, DEPRESSIVE SYMPTOMS, AND HEART DISEASE

Sponsored by: Columbia University, National Alliance for Research on Schizophrenia and Depression

Depressive symptoms and inflammatory markers have both been proposed as measures that indicate/precede coronary artery disease. However, no controlled research study has tested the effect of these two candidate risk factors within the same design to see the directionality of their influence. This study will explore whether simvastatin reduces depressive symptoms and whether sertraline reduces C-reactive protein. Additionally, the recruitment process will help determine the feasibility of a larger trial, powered for significance testing. Three hundred and seventy-five participants will be screened for this study. We expect 42 otherwise healthy outpatients to have both elevated

symptoms and high C-reactive protein levels and be willing to be randomly assigned to sertraline, simvastatin, or a placebo for eight weeks. Depressive symptoms and inflammatory indicators will be assessed before treatment (screening and baseline), mid-treatment (after four weeks), post-treatment (after eight weeks), and at a follow-up visit (after 12 weeks) by using blood tests and depression interviews. We expect that both inflammation and depressive symptoms may be reduced by both medications, but the number of subjects needed to test this hypothesis is not yet known. Hence, this pilot study will be conducted. Knowledge about the interdependency of these

two risk factors will allow the most promising future observational/intervention studies to be designed and conducted

Inclusion criteria: age 18–60 years, mild depression, C-reactive protein >2 .

Exclusion criteria: non-English or non-Spanish speaking, active suicidal or homicidal ideation, current alcohol or other substance abuse, psychotic features, current personality disorder, history of bipolar depressive disorder, any current psychotic disorder, current major depressive disorder, current depression treatment or treatment within preceding six weeks, history of chronic liver and/or renal disease, current use or contraindication to any of the tested

medications, absence of a response to a previous adequate trial of any of the tested medications, pregnant or lactating women, history of coronary artery disease, current use of statins, regular aspirin use, antibiotic use within the previous four weeks, history of diabetes, inflammatory disease.

Study start: April 2005

Study end: March 2008

This study is currently recruiting patients. Contact Karina W Davidson, PhD, Columbia University Department of General Medicine, New York, New York; 212-342-4493; kd2124@columbia.edu.