

# CLINICAL RESEARCH RELATED TO ETHNIC MINORITY HEALTH

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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](http://www.clinicaltrials.gov). The information below was accurate at press time; the study researchers should be contacted for more information.

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## MEDICINAL PLANT USE FOR TREATING INFLAMMATION AMONG DOMINICANS IN NEW YORK CITY AND THE DOMINICAN REPUBLIC

Sponsored by: National Center for Complementary and Alternative Medicine

According to the 2000 US Census report, Dominicans constitute the largest Hispanic immigrant group in New York City. Studies have shown that immigrants' use of traditional and herbal medicine is close to that of native-born Americans. However, minority immigrants often have limited access to traditional health care; as a result, they may be more likely to consult with traditional healers and use medicinal plants than nonimmigrants. This study is designed to increase knowledge about immigrants' health and to contribute to more culturally

sensitive health care. The purpose of this study is to determine medical plant knowledge and use among Dominican traditional healers and patients in New York City and in the Dominican Republic.

This study will comprise two parts. In part I, Dominican medicinal plant users and Dominican traditional healers in New York City will be questioned about the medicinal plant species they know and how they are used for prevalent illnesses. The same number of participants will be interviewed in the Dominican Republic, allowing

for detailed comparisons between the two study sites.

In part II, the most frequently cited medicinal plant species will be subjected to a thorough literature review on their pharmacologic activity and the chemical composition of their active constituents. Two in vitro assays will be used to measure the antiinflammatory activity of certain plant extracts, and their antiinflammatory compounds will be isolated and characterized for the purpose of standardization of active extracts. On the basis of these results, recommendations will be formulated for future

studies and community use of selected medicinal plant species.

Inclusion criteria: age  $\geq 18$  years, Dominican ethnicity, knowledge of Dominican medicinal plants.

Study start: March 2005  
Study end: January 2008

This study is recruiting patients. Contact Rafael Lantigua, MD, New York Associates in Internal Medicine Clinic, New York-Presbyterian Hospital, Columbia University, New York, NY 10032, USA; phone: 212.305.6262; [ral4@columbia.edu](mailto:ral4@columbia.edu).

## EVALUATION OF INTERACTION BETWEEN HERBAL PRODUCTS AND ANTICOAGULANTS

Sponsored by: National Center for Complementary and Alternative Medicine

The purpose of this study is to determine if the use of herbal products interferes with normal anticoagulation, leading to either excessive thinning of the blood and bleeding problems or inadequate thinning of the blood and clotting problems. Many patients who are on long-term anticoagulation for a variety of

medical problems also take herbal products. Whether use of herbal products interferes with this anticoagulation and puts patients at risk for bleeding or clotting is unknown. This study will carefully monitor patients who are taking herbs and anticoagulants to determine if their laboratory tests show signs of

being affected by the herbs. The study will ask all patients about their herbal product use, so all reported herbs will be included and monitored.

Inclusion criteria: taking long-term ( $>6$  months) anticoagulation, enrolled in one of Kaiser Permanente Northern California anticoagulation clinics.

Study start: January 2006  
Study end: December 2007

This study was not recruiting patients as of press time. Contact Stephen Bent, MD, University of California, San Francisco.

**SERTRALINE COMPARED WITH *HYPERICUM PERFORATUM* (ST. JOHN'S WORT) IN TREATING MILD-TO-MODERATE DEPRESSION IN PATIENTS WITH CANCER**

Sponsored by: Comprehensive Cancer Center of Wake Forest University and National Cancer Institute

Antidepressants such as sertraline and the herb *Hypericum perforatum* (St. John's wort) may be effective in treating mild-to-moderate depression. This randomized phase III trial is studying how well sertraline works compared to St. John's wort in treating mild-to-moderate depression in patients with solid tumors.

This is a randomized, double-blind study. Patients are stratified according to level of depression (mild vs moderate),

concurrent radiotherapy (yes vs no), and TNM stage (I, II, or III vs IV). Patients are randomized to either oral sertraline daily or oral *Hypericum perforatum* daily. In both arms, treatment continues for 4 months in the absence of unacceptable toxicity. Measurements of depression, somnolence, nausea, insomnia, fatigue, and hyperforin concentration are assessed at baseline, and at 1, 2, and 4 months.

Inclusion criteria: age  $\geq 18$  years, histologically or cytologi-

cally confirmed solid tumor, mild to moderate depression, hemoglobin  $>10$  g/dL, at least 4 weeks since previous chemotherapy, at least 4 weeks since previous antidepressants or *Hypericum perforatum*.

Exclusion criteria: hematologic malignancy, psychotic symptoms, dementia, brain metastases or primary brain tumor, bilirubin  $>1.5$  mg/dL, pregnancy, alcohol abuse, drug abuse, epoetin alfa, corticosteroids, warfarin, theophylline, protease inhibitors,

digoxin, cyclosporine, benzodiazepines, calcium-channel blockers, coenzyme A reductase inhibitors, macrolide antibiotics, griseofulvin, phenobarbital, phenytoin, rifampin, rifabutin, ketoconazole, fluconazole, itraconazole, grapefruit juice, herbal products that would interfere with *Hypericum perforatum*.

This study is recruiting patients. For more information: <http://clinicaltrials.gov/show/NCT00066859>.

**COMPLEMENTARY AND ALTERNATIVE MEDICINE USE IN LOW-INCOME AFRICAN-AMERICAN AND CAUCASIAN ADULTS WITH ASTHMA**

Sponsored by: National Center for Complementary and Alternative Medicine

The rates of asthma-related death and disease are disproportionately high among African Americans compared to Caucasians. Surveys indicate that middle- and upper-income Caucasians use more complementary and alternative medicine (CAM) than African Americans, but therapies used are different. This study will determine how well people with persistent asthma adhere to their treatment and whether the type and frequency of use

of CAM affects treatment adherence.

Participants will begin this study by taking part in an interview about adherence to their current inhaled corticosteroid (ICS) regimen and their personal CAM use. After completing the interview, participant adherence to their ICS regimen will be monitored for 6 weeks. Depending on the type of ICS participants are taking, monitoring will be conducted either by participant self-report or elec-

tronic monitors that record the time and date of medication inhalation. Participant adherence will also be assessed at study completion.

Inclusion criteria: age 21–50 years, physician-diagnosed asthma with episodes that last for long periods of time, Medicaid recipient, self-identify as African American or Caucasian, daily use of inhaled corticosteroids, ability to speak English, mental capacity to understand and participate in the study.

Exclusion criteria: incarceration, history of smoking  $\geq 10$  packs of cigarettes per year, currently smoke  $>1.5$  packs of cigarettes per week.

Study start: November 2004

This study is recruiting patients. Contact Maureen George, PhD, RN, Johns Hopkins Bayview Campus, Baltimore, MD 21224, USA; 410.550.4889; [mgeorg16@jhmi.edu](mailto:mgeorg16@jhmi.edu).