

CLINICAL RESEARCH

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.

OSI-774 IN AFRICAN AMERICAN PATIENTS WITH ADVANCED AND PREVIOUSLY TREATED NON-SMALL CELL LUNG CANCER

Sponsored by: Ohio State University Comprehensive Cancer Center

Researchers are seeking to identify treatment regimens with low toxicity for non-small cell lung cancer (NSCLC), especially for African Americans with this disease who seem to have a larger burden of co-morbidities and decreased performance status. The current study uses a drug called OSI-774 in previously treated African American patients with NSCLC. OSI-774 is a targeted agent designed as an EGFR tyrosine kinase inhibitor. Previous research indicates that tumor cells overexpress EGFR

receptors, and this drug works by blocking these receptors on tumor cells that help them grow.

The primary objective of this study is to determine the objective tumor response rate, the time to tumor progression, and the survival rate at one year produced by OSI-774 in previously treated African American patients with advanced NSCLC. A second objective is to evaluate if a regimen of single-agent OSI-774, with dosing initially influenced by body weight and with

subsequent titration to achieve skin rash, is a suitable regimen for future studies of this agent. A third objective is to measure if changes in EGFR from tumor and blood cells correlate with the development of rash and clinical benefit. The pharmacokinetics of OSI-774 will also be characterized through study participants.

Inclusion criteria: age ≥ 18 years, histologically or cytologically confirmed stage IIIB or IV NSCLC treated with 1–2 platinum- or taxane-containing regi-

mens, measurable disease, African American ethnicity.

Exclusion criteria: known brain metastases, prior treatment with EGFR-targeting therapies, pregnant/lactating women.

This study is not yet recruiting patients. Contact Ohio State University Cancer Clinical Trial Matching Service, Columbus, OH 43210, USA; phone: 866-627-7616; osu@emergingmed.com.

PATIENT-CENTERED DEPRESSION CARE FOR AFRICAN AMERICANS

Sponsored by: Agency for Healthcare Research and Quality

Several studies document underutilization of outpatient specialty mental health services by African Americans. However, African Americans with depression are just as likely as Whites to receive care in primary care settings. Despite their use of primary care services, African American patients are less likely than Whites to be recognized as depressed, offered pharmacotherapy, and to initiate or complete pharmacotherapy or psychotherapy for depression. Compared to Whites,

African American patients express stronger preferences for counseling and more negative attitudes toward antidepressant medication, the most common form of treatment of depression used by primary care physicians. African Americans are also more likely to see depression and its treatment through a spiritual or religious framework. Studies show that African Americans receive less optimal technical and interpersonal health care than Whites for many conditions.

Investigators have created a patient-centered adaptation that includes many of the components of recent successful quality improvement interventions for depression in primary care. The proposed study compares a standard depression intervention for patients (delivered by a depression case manager) and physicians (review of guidelines and structured mental health consultation) to a patient-centered intervention for patients (incorporates patient activation, individual preferences,

and cultural sensitivity) and physicians (incorporates participatory communication skills training with individualized feedback on interactive CD-ROM). Thirty physicians and 250 patients will be randomized to either the standard interventions or the culturally tailored interventions. The main hypothesis is that patients in the patient-centered, culturally tailored intervention group will have higher remission rates from depression and lower levels of depressive symptoms at

12 months than patients in the standard intervention care group. Secondary outcomes will include patient receipt of guideline-concordant care, patient and physician satisfaction with care, patient-physician communication behaviors, patient and physician attitudes towards depression, and self-efficacy in managing depression. This study will add to knowledge about how to effectively engage African American

patients in care of depression and serve as a prototype of how to incorporate patient-centeredness in programs to reduce racial and ethnic disparities in health care for common conditions.

Inclusion criteria: age 18–75 years, two weeks or more of depressed mood/ loss of interest in the past year, one week or more of depressed mood or loss of interest in the past month, self-defined African American

ethnicity, ability to give written consent.

Exclusion criteria: current alcohol or drug abuse, history of mania, grief reaction or bereavement within the past 2 months, pregnancy, life expectancy <1 year, non-English speaking, current specialty mental health care (at least 2 visits in past 6 weeks and appointment scheduled in future), plan to change health-care or primary care provider in

next 12 months, active suicidal thoughts and plans, residing in United States <5 years.

Study start: March 2004
Study end: March 2008

This study is currently recruiting patients. Contact Bri K. Ghods, phone: 410-522-6500, ext. 263; bghods@jhmi.edu

CAN EDUCATION FOR SOUTH ASIANS WITH ASTHMA AND THEIR CLINICIANS REDUCE UNSCHEDULED CARE? A RANDOMISED TRIAL

Sponsored by: Barts & The London NHS Trust

Health inequalities between ethnic minority and majority groups exist for all chronic diseases and are a government priority for action. For asthma, poorer outcomes for people from minority groups are a universal finding. No randomized trials have reduced emergency asthma care for ethnic minority groups.

We have developed an intervention to address barriers to improved asthma care for south Asian people with asthma. This cluster-randomized controlled trial tests whether education for south Asians with asthma and their clinicians can reduce unscheduled care. The trial is set in

Tower Hamlets and Newham, boroughs with the United Kingdom's first and third highest ethnic minority populations.

We will recruit south Asians age 3–65 years with asthma after hospital admission. Participants registered with intervention practices will see the trial specialist nurse in a nurse-run hospital clinic, where the nurse provides self-management advice and a treatment plan, makes a follow-up appointment for the patient in primary care and makes an appointment for lay-led "expert-patient" sessions. Participants registered with control practices receive usual care. Primary outcomes are time to

first unscheduled contact with acute asthma and proportion of participants with unscheduled care, assessed from patient records 12 months after recruitment.

Inclusion criteria: age 3–65 years, recent hospital attendance with uncontrolled asthma or recent out of hours walk-in center attendance with uncontrolled asthma, south Asian ancestry (Bangladeshi, Indian, Pakistani, Sri Lankan), registered with a general practitioner in Newham or Tower Hamlets.

Exclusion criteria: not of South Asian origin, age <3 years, not currently registered with a local general practitioner, phy-

sician diagnosis of pure chronic obstructive pulmonary disorder, inability to give informed consent.

Study start: November 2005
Study end: September 2008

This study is not yet recruiting patients. Contact Chris Griffiths, MB BS, DPhil; Barts and The London, Queen Mary's School of Medicine and Dentistry, London, E1 4NS, United Kingdom; phone: 44-0207-882-2501; c.j.griffiths@qmul.ac.uk

USE AND DECISIONMAKING ABOUT COLORECTAL CANCER SCREENING AMONG HISPANIC MEN AND WOMEN

Sponsored by: Centers for Disease Control and Prevention

During the first year, researchers worked toward identifying factors influencing initiation of

colorectal cancer screening among Hispanic men and women age ≥ 50 years and developing an

intervention plan using intervention mapping, a framework for systematic health promotion pro-

gram planning, implementation, and evaluation. Researchers are also in the preliminary stages of

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developing two lay health worker-delivered interventions: a small media intervention (video, flip-chart, pamphlets) and a tailored interactive multimedia intervention, before the actual collection of data. Thus, although 733 subjects have been approved by the Committee for the Protection of Human Subjects to be enrolled

in this study in the future, no subjects have been enrolled at this time. Since the risks associated with participating in this study are negligible, the researchers do not anticipate any adverse events in the future. No modifications have been made to the research since the last review, other than that the researchers are currently

reassessing the need to conduct preliminary qualitative research as proposed in the original protocol.

Inclusion criteria: age ≥ 50 years.

Exclusion criteria: history of colorectal cancer.

Study start: October 2005

Study end: September 2008

This study is not yet recruiting patients. Contact Maria E. Fernandez, PhD, University of Texas, Houston, TX 77225, USA; phone: 713-500-9626; Maria.E.Fernandez@uth.tmc.edu