

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.

REDUCING HIV: SAFER SEX SKILL BUILDING IN PREGNANT, DRUG-ABUSING WOMEN

Sponsored by: the Virginia Commonwealth University and the National Center on Minority Health and Health Disparities

This study will focus on increasing safer sex skills development among pregnant women at high risk for HIV infection. The Safer Sex Skill Building (SSB) program has demonstrated efficacy in national studies in reducing sexual risk for HIV and other sexually transmitted disease transmission. This manual-driven, sex-specific intervention has proven effective in reducing sexual risk behaviors in both methadone maintenance and outpatient drug-free patients. To date, however, the intervention has not been tested with

pregnant, drug-abusing women who may actually be at increased risk if they stop using condoms or continue drug use during pregnancy. This study will examine SSB, a targeted behavioral HIV prevention and risk reduction intervention, in two samples of pregnant, drug-abusing women. Using a 2×2 design, a randomized clinical trial will compare the five-session SSB group intervention to a one-session standard group HIV education intervention. Study findings will provide benchmark data on the efficacy of SSB for

HIV and sexually transmitted disease prevention in a diverse sample of pregnant, drug-abusing women.

Inclusion criteria: age ≥18 years; pregnant; screen positive on T-ACE, TWEAK, or drug CAGE; report drinking three or more drinks on at least one occasion or using an illicit drug at least once in the 30 days before pregnancy awareness; report at least one incident of unprotected penetrative (vaginal or anal) intercourse with a male partner in the six months before baseline assessment.

Exclusion criteria: inability to provide informed consent because of cognitive impairment, psychiatric instability, or language barriers.

Study start: April 2008

Study end: October 2012

This study is not yet open for participant recruitment. Contact Diane M. Langhorst, PhD; Virginia Commonwealth University; Richmond, Virginia; 804-827-2524; dlanghorst@vcu.edu.

IDENTIFICATION OF EFFECTIVE INTERVENTION STRATEGIES TO INCREASE THE NUMBER OF HIV-INFECTED ETHNIC MINORITIES ENROLLED IN AIDS CLINICAL TRIALS

Sponsored by: the National Institute of Allergy and Infectious Diseases

Preliminary research suggests that intensive intervention efforts are needed to improve rates of screening and to enroll more ethnic minorities and women in AIDS clinical trials. The purpose of this study is to identify effective intervention strategies to increase the number of HIV-infected ethnic minorities and women who are screened for

and enrolled into AIDS clinical trials.

Each participant will be enrolled in the study for 12 months. Participants will be randomly assigned to either the intervention or control arm. Initial “seed” participants in the intervention arm will complete a peer-driven intervention consisting of four structured

intervention sessions lasting six hours in total (every week for four weeks), three peer education/recruitment experiences, and brief liaison contacts by an intervention facilitator during AIDS clinical trial screening. Participants in the control arm will complete a time-matched health education intervention lasting six hours. Participants in

the control arm will also receive the community standard of care and be referred to their local clinical trial unit. Peer participants will be recruited by either a seed or through general recruitment; those recruited by an initial seed will participate in the same arm as the seed who recruited them. Study visits will occur throughout the study.

CLINICAL RESEARCH

Participants in the intervention arm will complete an interview at week 30. At weeks 8, 16, and 52, all participants will complete social impact assessments. At weeks 16 and 52, all participants will complete follow-up visits.

Inclusion criteria: age ≥ 18 years, HIV infection, seen at the Betances Health Center or AIDS Service Center at least once in the last six months before study entry, African American or Latino ethnicity, willing to recruit HIV-infected

peers, ability to speak and write in English.

Exclusion criteria: current enrollment in an HIV/AIDS clinical trial; current psychosis based on standard assessment, any condition that would interfere with participation in the study.

This study is not yet open for participant recruitment. Contact Marya V. Gwadz, PhD; Center for Drug Use and HIV Research, Institute for AIDS Research, National Development and Research Institutes, Inc.

PROSPECTIVE STUDY OF METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS* AMONG HIV-INFECTED PERSONS

This study will prospectively evaluate the prevalence and incidence (over a two year period) of MRSA colonization and infection among HIV-infected military beneficiaries to determine predictors for the development of MRSA colonization and infection. This study will also investigate the utility of decolo-

nization procedures for clearance of MRSA carriage and prevention of MRSA infections. Finally, the molecular characteristics and the antimicrobial sensitivities of isolates in this population will be determined.

Inclusion criteria: age ≥ 18 years, HIV positive, ability to attend study visits.

Sponsored by: the Uniformed Services University of the Health Sciences, Infectious Diseases Clinical Research Program, National Institute of Allergy and Infectious Diseases, US Military HIV Research Program

Exclusion criteria: allergy to mupirocin nasal ointment or hexachlorophene soaps or constituents of these products; inability to remain in the study for the two-year duration; pregnant or breastfeeding; intention to become pregnant during the study; healthcare providers with direct patient contact.

Study start: May 2007
Study end: May 2011

This study is currently recruiting participants. Contact Nancy Crum-Cianflone, MD; Naval Medical Center San Diego/Infectious Disease Division; San Diego, California; 619-532-7475; nancy.crum@med.navy.mil.

IMPACT OF HIV INFECTION ON LATENT TUBERCULOSIS (TB) AMONG PATIENTS WITH HIV-TB COINFECTION

During the natural course of HIV disease, emergence of opportunistic infection facilitates viral replication, leading to faster disease progression. TB, the most common opportunistic infection among HIV-infected persons, deserves special attention. HIV has recently been reported to preferentially

infect, destroy, and incapacitate two key immune-regulatory T-cell subsets, namely NKT and Treg cells. Therefore, studying them along the course of HIV disease and the effect of changes to them on the function of effector T cells directed against *Mycobacterium tuberculosis* is important.

Sponsored by: the All India Institute of Medical Sciences, Indian Council of Medical Research, India Ministry of Science and Technology

Study start: July 2008
Study end: March 2010

Inclusion criteria: age 18–65 years, HIV infection (for some participants), antiretroviral drug-naïve, TB (for some participants), ability to give informed consent.

Exclusion criteria: pregnant or breastfeeding, steroid therapy,

diabetes, malignancy, chronic renal failure, liver disease, cytotoxic therapy, living outside of Delhi.

This study is not yet open for participant recruitment. Contact Surendra K. Sharma, MD, PhD; All India Institute of Medical Sciences; 26594415; surensk@gmail.com.