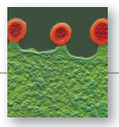

Open Clinical Trials for Patients With HIV and/or Hepatitis B and C

Web-Based Intervention to Reduce Alcohol Use in Veterans With Hepatitis C

The primary objective of this study is to implement and evaluate a web-based brief alcohol intervention (BAI) for treating veterans with hepatitis C virus (HCV) and seeking care at 2 VA HCV clinics–VAPAHCS and SFVAMC. This study will have 3 aims: First, the investigators plan to assess patient, provider, and system factors that may impact the initial adoption of this intervention in 2 VA HCV clinics. These data will result in the development of a protocol for the initial implementation of the web-based BAI at the investigators' 2 study sites. A secondary aim will involve obtaining patient and provider feedback on an existing web-based BAI (see www.bmi-aft.org, VA intranet only) to help inform its redesign for use with this population. Second, the investigators will implement and examine the effectiveness of a web-based BAI in 2 HCV clinics to reduce alcohol consumption in veterans with HCV at 3- and 6-months post-treatment. Third, the investigators will conduct a budget impact analysis to estimate the short-term costs (1-3 years) of adoption and diffusion of the web-based BAI and the trajectory of health care spending for study participants.

ID: NCT01707030
Sponsor: VA Office of Research and Development
Location (contact): VA Palo Alto Health Care System, California (Keith Humphreys); San Francisco VAMC, California (Alex Monto)

Pilot Study of the Effect of Rifaximin On B-Cell Dysregulation in Cirrhosis

Hepatitis C is the leading cause of chronic liver disease and cirrhosis in U.S. veterans. Cirrhosis is associated with impaired antibody responses and increased risk of bacterial infections. We have recently identified that cirrhosis is associated with abnormalities of memory B-cells, cells that make antibodies and help protect against bacterial infections. We have identified that chemicals associated with gut bacteria might play a role in causing these B-cell abnormalities. It is well known that gut bacteria have increased access to the blood in individuals with cirrhosis, a process called bacterial translocation. We hypothesize that reducing bacteria counts in the gut by using poorly-absorbed antibiotics (also known as selective gut decontamination) will partially reverse losses of memory B-cells in cirrhosis by reducing bacterial translocation.

ID: NCT01951209
Sponsor: David E. Kaplan, MD MS
Location (contact): Corporal Michael J. Crescenz VAMC, Philadelphia, Pennsylvania (David Kaplan)

Long-Term Study of Liver Disease in People With Hepatitis B and/or Hepatitis C With or Without HIV Infection

The primary objective of the proposed study is to characterize viral liver disease and factors affecting the natural history of viral liver disease in persons with and without HIV with an emphasis on those living in the Washington DC metropolitan area. There are few longitudinal research cohorts of participants with viral hepatitis and HIV coinfection, especially at integrated medical care centers. The study, including a participant questionnaire for HCV infected participants only and phlebotomy, will be administered on-site at clinical facilities in the District of Columbia and at the National Institutes of Health. The cohort will be designed to study research questions with respect to liver disease, disease pathogenesis using genomics, proteomics, and immunologic disease models. Secondary objectives include study of the immunopathogenesis of hepatitis B virus (HBV) and HCV disease progression in HIV-infected subjects. In addition, this is an invaluable opportunity to determine the prevalence and risk factors associated with the development of hepatocellular carcinoma, the long-term effects of HCV clearance with direct-acting antivirals (DAAs), along with biomarker profile(s) for diagnosis and outcome. Moreover, this will serve as a catchment protocol to select appropriate participants for novel HBV and HCV therapeutic trials.

ID: NCT01350648
Sponsor: National Institutes of Health Clinical Center
Location: Washington DC VAMC; National Institutes of Health Clinical Center, Bethesda, Maryland

Evaluating the Use of Pitavastatin to Reduce the Risk of Cardiovascular Disease in HIV-Infected Adults (REPRIEVE)

Currently, there are few strategies to prevent cardiovascular disease (CVD) in HIV-infected people, even though they are at high risk for developing CVD. Statin medications are used to lower cholesterol and may be effective at reducing the risk of CVD in people infected with HIV. The purpose of this study is to evaluate the use of pitavastatin to reduce the risk of CVD in adults infected with HIV who are on antiretroviral therapy (ART). This study will enroll adults infected with HIV who are on any ART regimen (ART is not provided by the study) for at least 6 months before study entry considered low-to-moderate risk using the 2013 American College of Cardiology/American Heart Association guideline thresholds for

recommended statin initiation. Total study duration will be approximately 72 months from the time the first participant is enrolled.
ID: NCT02344290
Sponsor: National Institute of Allergy and Infectious Diseases (NIAID)
Location (contact): VA West Los Angeles Medical Center CRS, California (Wendy Rossen); VA Connecticut Healthcare System CRS, West Haven (Laurie Andrews); Washington DC VAMC; Malcom Randall VA Medical Center CRS, Gainesville, Florida (Evan Waters); VA New York Harbor Healthcare System (Christine Reel-Brander); Dallas VAMC, Texas (Ashley Liggion-Turk); Michael E. DeBakey VAMC, Houston, Texas (Mahwish Mushtaq)

Development of a City-Wide Cohort of HIV-Infected Persons in Care in the District of Columbia: The DC Cohort

All major community and academic clinics treating HIV-infected persons in the District of Columbia (DC) will initially be included in the development of a city-wide "DC Cohort" of HIV-infected persons in care, with consideration to be given subsequently to the inclusion of large private physician practices. Socio-demographics, risk factors, treatments, diagnoses, labs and procedures documented in outpatient medical record systems will be included in the DC Cohort database. Routine reports will be generated every 6 months for sites comparing their participants' socio-demographics, clinical status, treatments, and outcomes to all other data in the DC Cohort database, and other comparisons specifically requested by sites. All sites will be provided analytic support in research areas of interest.
ID: NCT01206920
Sponsor: George Washington University
Location: Washington DC VAMC

Study of Immune Responses Induced by a HIV Vaccine

The primary purpose of this study is to define in HIV-uninfected volunteers the innate, cell-mediated and humoral responses induced by AIDSVAX B/E in the systemic and mucosal compartments and to characterize B cell functional specificities in peripheral blood, bone marrow and sigmoid compartments.
ID: NCT01933685
Sponsor: U.S. Army Medical Research and Materiel Command

Strength Training and Endurance Exercise for LIFE (STEEL)

The objective of this study is to determine the effect of exercise training on the central (cardiovascular) and peripheral (muscular) impairments underlying poor physical function by comparing older HIV-infected veterans randomized to combine aerobic and resistance exercise training versus usual care. The study hypothesis is that a progressive aerobic and resistance rehabilitation program will increase aerobic capacity and muscle strength, which will be mediated by improved diastolic function, increased muscle mass, and decreased systemic inflammation. To test this hypothesis, investigators will conduct a randomized 16-week trial of progressive aerobic and resistance training versus usual care control in 40 sedentary older (50+ years) HIV-infected veterans. The study will determine the effects of exercise training on aerobic capacity and diastolic function, and their relationship to changes in biomarkers of systemic inflammation and cardiac fibrosis (AIM 1). The study also will determine the effect of exercise training on strength and muscle mass, and their relationship to changes in biomarkers of systemic inflammation (AIM 2).
ID: NCT02101060
Sponsor: VA Office of Research and Development
Location (contact): Salem VA Medical Center, Virginia (Carolyn Jones, Tracy A Hicks)