

ACTG Launches IPACE-HIV to Study Frailty Intervention

This Phase II study will evaluate the safety and efficacy of dasatinib and quercetin for improving physical function outcomes in people living with HIV who are frail or at risk for frailty.

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CHAPEL HILL, N.C. — ACTG, a global clinical trials network focused on HIV and other infectious diseases, today announced the opening of the IPACE-HIV study (Improving Physical Ability and Cellular Senescence Elimination in HIV), also known as A5426. IPACE-HIV is a Phase II, double-blind, randomized study evaluating the safety, tolerability, and efficacy of dasatinib and quercetin in improving physical function outcomes in people living with HIV who are frail or exhibit symptoms that they may become frail.

People living with HIV often experience diseases and conditions, including frailty, that are associated with aging at younger ages than people who are not living with HIV. This is true even among individuals whose HIV is well-controlled on antiretroviral treatment (ART).

Current treatment for physical function impairment and frailty in people living with HIV focuses on non-pharmacologic interventions such as exercise, nutritional support, and management of the comorbidities that can contribute to frailty. Dasatinib and quercetin are senolytics, drugs targeting the cells that play a role in biologic aging. Clinical trials involving this regimen have shown promise in reversing some of the symptoms and signs of frailty, but to date these studies have not included people living with HIV.

“ACTG is excited to undertake the first carefully controlled study evaluating senolytics as a potential intervention against frailty among people living with HIV,” said ACTG Chair Joseph J. Eron, MD, University of North Carolina. “This approach is exciting because it focuses on altering what may be the underlying cause of age-related conditions instead of the conditions themselves.”

IPACE-HIV is a multi-center trial that will enroll 80 participants age 50 and older who were diagnosed with HIV at least 10 years ago, are currently virally suppressed on ART, meet at least one frailty criteria (using the Fried Frailty Evaluation), and have a slower than normal speed on the four-meter walk test. Study participants will be randomized to either receive dasatinib and quercetin or placebos for 12 weeks and followed for an additional 12 weeks to evaluate the durability of the regimen’s effect on physical function.

“For many reasons, physical exercise may not always be an option for people living with HIV who experience frailty and age-related illness,” said Study Co-Chair Mary Clare Masters, MD, Montefiore Medical Center and Albert Einstein College of Medicine. “Furthermore, exercise, while an important intervention, may not address the underlying cause of these conditions. As we endeavor to provide HIV treatment that addresses the whole person, it is important to expand our outcome measurements beyond viral suppression to include quality of life. We look forward to understanding whether this approach could positively impact the rates of frailty and co-morbidities among people living with HIV and thus make a meaningful difference in their lives as they age.”

IPACE-HIV is led by Dr. Masters and Adam Spivak, M.D., University of Utah School of Medicine (Co-Chairs) and Frank Palella, MD, Northwestern University (Vice Chair). ACTG is led by Dr. Eron and Rajesh T. Gandhi, MD, Massachusetts General Hospital and Harvard Medical School (ACTG Vice Chair). It is sponsored by the National Institutes of Health’s (NIH) National Institute of Aging (NIA) and National Institute of Allergy and Infectious Diseases (NIAID, which also funds ACTG) under award numbers UM1 AI068636, UM1 AI107716, and UM1 AI068634.

For more information about IPACE-HIV, please visit clinicaltrials.gov.

About ACTG

ACTG is the world’s largest and longest running clinical trials network focused on HIV and other infectious diseases and the people living with them. It is funded by NIAID and collaborating NIH Institutes. Founded in 1987, ACTG conducts research to improve the management of HIV and its comorbidities; develop a cure for HIV; and innovate treatments for tuberculosis, hepatitis B, and emerging infectious diseases. It comprises thousands of dedicated researchers, staff, and community members who are pursuing research into novel treatments and cures for infectious diseases at 65 locations across four continents, with the ultimate goal of advancing science that meaningfully impacts the lives of the people we serve.

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