Case Western Reserve University/University Hospitals Case Medical Center
AIDS Clinical Trials Unit

A5350 Clinician Summary: Safety, Tolerability, and Effects of the Probiotic Visbiome Extra Strength on Gut Microbiome and Immune Activation Markers in HIV-Infected Participants on Suppressive Antiretroviral Therapy: A Phase II Study

Brief Summary:
A5350 is a randomized, double-blind, placebo-controlled, two-arm pilot study to determine the safety and tolerability of 24 weeks of probiotic Visbiome Extra Strength (Visbiome ES) therapy, and to evaluate for significant change in sCD14. Participants will be followed for an additional 12 weeks following the 24 weeks of trial produce usage. An optional substudy, A5352s, will be conducted in a subset of participants to collect colonic biopsies via flexible sigmoidoscopy, and evaluate intestinal permeability and inflammation at two time points.

Study Population:
HIV-positive men and women,≥18 years of age;
On continuous ART ≥ 48 weeks and on stable ART ≥ 24 weeks prior to study entry;
CD4+ T-cell count >200 cells/mm^3;
HIV-1 RNA <50 copies/mL for 48 weeks prior to study entry (one blip ≤500 allowed);
No history of positive HCV antibody with detectable HCV RNA within 48 weeks of study entry;
No history of positive HBsAg within 48 weeks of study entry;
No liver cirrhosis, history of inflammatory bowel disease, total colectomy, colon or rectal anastomosis, bowel resection or current colostomy;
No current diagnosis of diabetes;
Some restrictions of use of following within 60 days of study entry: immunosuppressives; immune modulators; antineoplastic agents; and probiotics and prebiotics (yogurt with live cultures is allowed);
No history of lactose intolerance or milk allergy;
No weight loss or gain of 25 pounds or more within 24 weeks of study entry.

Treatment:
Participants will be randomized in a 1:1 ratio to either Arm A (Visbiome ES + stable ART; treatment arm) or Arm B (placebo for Visbiome ES + stable ART; control arm), such that 45 participants will be enrolled in each arm.

ARM A: Visbiome ES
2 week lead in period: 1 Visbiome ES sachet per day.
Then increase to 1 sachet twice daily for 22 weeks.
Followed by 12 weeks off study treatment

ARM B: Placebo for Visbiome ES
2 weeks lead in period: 1 placebo sachet per day.
Then increase to 1 sachet twice daily for 22 weeks.

Study Duration:
Participants will be on study for 38 weeks. There are 9 clinic visits during this period of time. Compensation is provided per visit. Bus ticket/parking provided at no cost. Gas cards provided for some transportation costs.

For more information about this trial, please contact
Kristen Allen, RN at 216-844-8136 or at allen.kristen@clevelandactu.org

www.clevelandhiv.org
June 1, 2016