Pharmacy and Poisons Board
Online clinical trials
Submitted Application : (ECCT/17/09/03)

Protocol No:	**ECCT/17/09/03**	Date of Protocol:	**19-04-2016**

Abstract of Study:

ABSTRACT

Human Immunodeficiency Virus (HIV) is an important global pandemic with an estimated 36.7 million people currently living with HIV and 2.1 million new HIV infections worldwide as per UNAIDS 2016 updates. In Kenya, the number of people living with HIV has been on the increase, and is currently estimated at 1.6 million while total new HIV infections were estimated to be 100,000 in 2013 as per the Kenya AIDS Response Progress report 2014. Recent studies have shown that early antiretroviral therapy (ART) improves both individual clinical outcomes, and decreases HIV transmission. Despite potent ART, HIV still persist due to the establishment of persistent cellular reservoirs of HIV-1 very early in acute HIV infection (AHI). Most proviral deoxyribonucleic acid (DNA) is in CD4+ T-cells, particularly central and transitional memory T-cells that persist through homeostatic, antigen-driven, or other mechanisms of proliferation. Very early antiretroviral therapy may limit the seeding of cellular reservoirs of HIV-1. Theoretically, ART initiated in the earliest Fiebig stages could limit the size and genetic diversity of the HIV-1 reservoirs, thereby improving the chance of an HIV-1 cure. This is a phase II, prospective, open-label study to measure the effects of early antiretroviral therapy on the establishment of HIV-1 reservoir and HIV-1-specific immunity. This study aims to compare the amount of cell-associated HIV-1 DNA (CAHD) in 5 million blood-derived CD4+ T-cells (assayed by quantitative PCR [qPCR]) at week 48 among participants who initiated ART in Fiebig I/II versus Fiebig III/IV versus Fiebig V and had sustained suppression of plasma HIV-1 RNA. Participants of 18 years and above with AHI will be enrolled and started on immediate study provided ART which is a single tablet of elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/COBI/FTC/TAF). Other non-study-provided ARV regimens provided through the PEPFAR program will be allowed for participants who are pregnant, breastfeeding, or unable or unwilling to take study provided ARV. A total of 150 participants will be enrolled, with Kericho site enrolling up to 10 participants. The study duration is up to 72 weeks. The information obtained from this study will be critical in designing therapeutic strategies and understanding the responses observed in future HIV cure-related studies

Study Title:

Effect of Antiretroviral Treatment Initiated During Acute HIV-1 Infection on Measures of HIV-1 Persistence and on HIV-1-Specific Immune Responses