

TICO

STUDY TITLE:	Virological and clinical anti-HBV efficacy of tenofovir in antiretroviral naive patients with HIV/HBV co-infection Protocol No : VHWG 001
STUDY OBJECTIVE:	The purpose of the study is to compare the effectiveness of 3 different treatment regimens in reducing or clearing the Hepatitis B Virus in patients infected with HIV and Hepatitis B (co-infection)
STUDY DESIGN:	Patients will be randomised to one of three treatment arms; tenofovir (TDF) vs lamivudine (LAM) vs TDF/LAM in antiretroviral naive subjects with HIV/HBV co-infection over 48 weeks.
STUDY DRUGS:	Patients will be randomly allocated to receive one of the three combinations of treatments below: Arm 1: Zidovudine (AZT), lamivudine (LAM), efavirenz (EFV) Arm 2: Zidovudine (AZT), tenofovir (TDF), efavirenz (EFV) Arm 3: Lamivudine (LAM), tenofovir (TDF), efavirenz (EFV)
STUDY COMPLETION DATE:	Recruitment stop date: 2006 Study closure date: 2007
IS THE STUDY OPEN TO ENROLLMENT?:	Yes To enter the study you will need to be between 18 and 70 years of age, be HIV positive (defined by a positive HIV), have active hepatitis B infection (defined by positive surface antigen test and detectable hepatitis B virus in the bloodstream), have never taken any antiretroviral drugs for the treatment of HIV or hepatitis B infection, have no evidence of liver failure, liver cancer or serious kidney problems that may effect your body's ability to cope with the trial medication, and have no evidence of any other serious cause of liver disease apart from hepatitis B infection.
NUMBER OF PATIENTS ENROLLED/TARGET ENROLLMENT:	36 HIV/ Hepatitis B co-infected participants
SPONSOR:	National Centre In HIV Epidemiology and Clinical Research (NCHECR) at University of New South Wales
PARTICIPATING SITES:	HIV NAT, Thailand St Vincents Hospital, NSW The Alfred Hospital, VIC Monash Medical Centre, VIC St Vincents Hospital, VIC
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