

## TICO Sub-Study

<b>STUDY TITLE:</b>	<b>TICO Viral Kinetics Sub-study</b>  <b>Protocol No : VHWG 001</b>
<b>STUDY OBJECTIVE:</b>	The purpose of this study is to compare how potent tenofovir is against the Hepatitis B virus in patients with and without HIV coinfection.
<b>STUDY DESIGN:</b>	A total of 15 HIV/Hepatitis B co-infected patients will be recruited from the main TICO study into the TICO viral kinetics sub-study (five from the lamivudine arm, five from the tenofovir arm and five from the lamivudine/tenofovir combination arm).  An additional 15 patients infected with Hepatitis B only (mono-infected) will be enrolled and randomised in the following manner: LAM (n=5), TDF (n=5) and combination TDF/LAM (n=5).
<b>STUDY DRUGS:</b>	Arm 1: Lamivudine (LAM), +/- anti-HIV drugs (EFV and AZT) Arm 2: Tenofovir (TDF) +/- anti-HIV drugs (AZT and EFV) Arm 3: Lamivudine (LAM), tenofovir (TDF) +/- anti-HIV drug (EFV)
<b>STUDY COMPLETION DATE:</b>	Recruitment stop date: 2006 Study closure date: 2007
<b>IS THE STUDY OPEN TO ENROLLMENT?:</b>	Yes  The inclusion and exclusion criteria for the TICO Viral Kinetics Sub-study participants are identical to those for the main TICO study except mono-infected must be HIV antibody negative
<b>NUMBER OF PATIENTS ENROLLED/TARGET ENROLLMENT:</b>	14/15 HIV/ Hepatitis B co-infected participants 0/15 Hepatitis B mono-infected participants
<b>SPONSOR:</b>	National Centre In HIV Epidemiology and Clinical Research (NCHECR) at University of New South Wales
<b>PARTICIPATING SITES:</b>	HIV NAT, Thailand St Vincent's Hospital, NSW The Alfred Hospital, VIC Monash Medical Centre, VIC St Vincent's Hospital, VIC
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