



SILCAAT

STUDY TITLE:	A phase III, multicentre, randomised study of the biological and clinical efficacy of subcutaneous recombinant, human interleukin-2 (SC rIL-2) in HIV-infected patients with low CD4+ counts receiving active antiretroviral therapy (SILCAAT).
STUDY OBJECTIVE:	The SILCAAT study is testing whether intermittent SC rIL-2 therapy in combination with antiretroviral therapy (ART) in patients with advanced HIV-1 infection will reduce the risk of AIDS and death compared to people receiving combination ART alone.
STUDY DESIGN:	<p>Patients are HIV-infected individuals with CD4+ T-cell counts between 50-299 cells/mL and plasma HIV-RNA <10,000 copies/mL on stable combination ART. Patients are randomised on a 1:1 basis to receive SC rIL-2 with ART or ART alone. There are six 5-day dosing cycles of SC rIL-2 in the first year and after this, cycles are given as required (often just once a year) in order to achieve the CD4+ T-cell "goal".</p> <p>1971 patients are enrolled and will be followed for an average of 5+ years. The long period of follow-up is needed because the risk of AIDS and death has already been greatly reduced with the use of combination ART.</p> <p>NCHECR performs two distinct roles. Firstly as a National Coordinating Centre (NTCC) for all the Australian sites conducting this study. Secondly as a Regional Coordinating Centre to support the study in both Australia and the sites in Argentina.</p>
STUDY COMPLETION DATE:	2010
IS THE STUDY OPEN TO PATIENT ENROLLMENT:	No (Enrollment closed: October 2002)
NUMBER OF PATIENTS ENROLLED:	1,971 worldwide (126 Australia)
STUDY DRUG:	Recombinant Interleukin-2 (rIL-2)

SPONSOR:	University of Minnesota, National Institutes of Allergy and Infectious Diseases (NAID) of the National Institutes of Health (NIH), USA. Prior to 14 th February 2003, this study was sponsored by Chiron Corporation
COLLABORATING SITES:	17 Sites (12 Australia, 5 Argentina)
CONTACT PERSON:	Dr. Sarah L. Pett, NCHECR, Tel: (+61-2) 9385 0900