



ESPRIT

STUDY TITLE:	A randomised, open-label, phase III, international study of subcutaneous recombinant interleukin-2 (SC rIL-2) in patients with HIV-1 infection and CD4 lymphocyte counts greater than or equal to 300 cells/mm ³ : E valuation of S ubcutaneous P roleukin in a R andomised I nternational T rial (ESPRIT)
STUDY OBJECTIVE:	The ESPRIT study is testing whether intermittent SC rIL-2 therapy in combination with antiretroviral therapy (ART) in patients with HIV-1 infection will reduce the risk of AIDS and death compared to people receiving combination ART alone.
STUDY DESIGN:	4150 patients have been randomised to receive either intermittent SC rIL-2 therapy in combination with antiretroviral therapy or antiretroviral therapy alone. There are 3 dosing cycles of rIL-2 in the first 6 months of the study; thereafter further dosing is guided by the CD4+ T-cell goal. All patients will be followed up on the study for 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. NCHECR personnel co-ordinate the conduct of this study in Argentina, Australia, Israel, Japan, Singapore and Thailand.
STUDY COMPLETION DATE:	2010
IS THE STUDY OPEN TO PATIENT ENROLLMENT:	No (Enrollment closed: May 2003)
NUMBER OF PATIENTS ENROLLED:	Globally 4150 In the countries coordinated by the NCHECR as follows: 205 patients in Australia 64 patients in Israel 365 patients in Thailand 20 patients in Singapore 554 patients in Argentina 25 patients in Japan
STUDY DRUG:	Recombinant Interleukin-2 (rIL-2)
SPONSOR:	Division of AIDS, National Institute of Allergy and Infectious Diseases (NAID) of the National Institutes of Health (NIH),

	USA.
COLLABORATING SITES:	48 sites in 6 countries: Japan, Thailand, Israel, Singapore, Argentina and Australia.
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