



STALWART

STUDY TITLE:	A Randomized, Open-Label, Phase II, International Study of Subcutaneous Recombinant Interleukin-2 (Proleukin®) with and without Concomitant Antiretroviral Therapy in patients with HIV-1 infection and CD4+ Cell Counts $\geq 300/\text{mm}^3$: Study of Aldesleukin with and without Antiretroviral Therapy (STALWART)
STUDY OBJECTIVE:	The purpose of this study is to compare the effects of intermittent cycles of subcutaneous rIL-2 administered with and without concomitant pericycle highly active antiretroviral therapy to no therapy on CD4 ⁺ T lymphocyte count in patients with HIV-1 infection and CD4 ⁺ T lymphocyte count ≥ 300 cells/mm ³ .
STUDY DESIGN:	<p>This is an international, phase II multi-site, open-label, randomized controlled study with three treatment arms. Eligible patients who provide consent will be randomized. Participants will be followed until a common closing date which will be 12 months after the last participant is randomized.</p> <p>Randomization (1:1:1) within strata defined by clinical site:</p> <p>Group A → N=160; No therapy</p> <p>Group B → N=160, rIL-2 (7.5 MIU sc q12 hours x 5 days q8 weeks x 3 cycles, then q8 weeks as needed to maintain counts at or above goal)</p> <p>Group C → N=160; rIL-2 (7.5 MIU sc q12 hours x 5 days q8 weeks x 3 cycles, then q8 weeks as needed to maintain counts at or above goal) + HAART (3 days prior to, 5 days during, and 2 days after rIL-2 cycle)</p>
IS THE STUDY OPEN TO PATIENT ENROLLMENT:	Yes, across all 8 Australian sites
ENROLLMENT TARGET:	480 worldwide with an equal allocation among the three study groups. Estimated 46 patients in Australia.
STUDY DRUGS:	Subcutaneous rIL2 7.5MIU given twice daily for 5 days every 6-10 weeks, 3 initial cycles in first six months of study, thereafter guided by CD4+ T-cell response.

SPONSOR:	Division of AIDS, National Institute of Allergy and Infectious Diseases (NAID) of the National Institutes of Health (NIH), USA.
COLLABORATOR SITES:	<p>3 countries comprise the Sydney Region</p> <p>THAILAND (4 sites)</p> <p>ARGENTINA (8 sites) and</p> <p>AUSTRALIA (8 sites)</p> <p>NSW: Holdsworth House General Practice, St. Vincent's Hospital</p> <p>QLD: Gladstone Road Medical Centre, AIDS Medical Unit, Gold Coast Sexual Health Clinic</p> <p>VIC: Carlton Clinic, Center Clinic</p> <p>WA: Royal Perth Hospital</p>
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