My, What a Big Trial IL-2 Has! Will It Work?

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When NIAID launched its five-year ESPRIT megatrial of IL-2 plus HAART vs. HAART alone, many hailed it as a long-overdue step toward funding much-needed immune-based-therapy research. But critics raised troubling questions ranging from dosage to bang-for-buck and more.

Consider:

Cost. Why spend so much on IL-2 when other promising but understudied immune-based therapies -- everything from therapeutic vaccines to the hormone DHEA to herbal combinations -- go begging?

Design. Will the varying cycle lengths (after six months the fixed schedule gives way to physician discretion) make data analysis impossible? And is five years long enough to see real differences in disease progression between those on HAART alone and those who spike it with IL-2?

Practicality. ESPRIT will require 2,000 HIVers with CD4s above 300 to self-inject, for five days every eight weeks, high-dose IL-2 plus down their tricky HAART regimens. Will enough healthy HIVers sign on to this rigorous, side effect-prone therapy to fully enroll the trial? The University of Colorado's Robert Schooley, MD, says, "You could be holding your breath for a long, long time."

Missed Opportunities. The trial's large size could yield important knowledge about new cell tests that might better measure immune changes, so why aren't samples of all participants' cells (instead of a limited number) being stored? Brenda Lein, director of Project Immune Restoration at Project Inform, says, "ESPRIT is useless in terms of answering the question of immune markers."

But NIAID official Jack Killen defends the trial. "It's taking big risks," he acknowledges, "but it's an important study that's been through an enormous amount of scrutiny."

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