

# International HIV/AIDS study is halted

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The U.S. National Institute of Allergy and Infectious Diseases says enrollment into an international HIV/AIDS trial has been halted.

The trial was to compare continuous antiretroviral therapy with episodic drug treatment guided by levels of CD4+ cells. But enrollment was stopped because patients receiving episodic therapy had twice the risk of disease progression into clinical AIDS or death.

NIAID made the decision to halt enrollment following a recommendation from an independent Data and Safety Monitoring Board that was charged with regularly evaluating data and safety issues during the multi-year trial.

The trial, known as Strategies for Management of Anti-Retroviral Therapy, or SMART, was designed to determine which of the two different HIV treatment strategies would result in greater overall clinical benefit.

The trial involved an international collaboration of 318 clinical sites in 33 nations. It began enrollment in January 2002 and had successfully recruited more than 90 percent of its target of 6,000 participants when enrollment was stopped.

The investigators say they will analyze the SMART study data to gain insights into the reasons for the increased risk.

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