

**Placebo-Controlled Trials of Zidovudine to  
Prevent Perinatal Transmission of HIV**  
(*NEJM*. 1997(Sep 18); 337:853-856)

The AIDS Clinical Trials Group (ACTG) Study 076 was the first randomized, controlled trial in which an intervention was proved to reduce the incidence of HIV infection. AZT had been administered orally to HIV-positive pregnant women in the U.S. and France, then administered intravenously during labor and subsequently administered to the newborn infants. This regimen reduced the incidence of HIV infection in newborns by two thirds and saved the life of one of every seven infants born to HIV-infected women. These findings were so highly significant that the study was terminated at the first interim analysis, and the U.S. Public Health Service recommended that the ACTG 076 regimen become the standard of care for HIV-positive pregnant women.

Because of the drug's high cost, women in developing countries could not gain access to the ACTG 076 regimen. Identifying less expensive interventions with similar effectiveness would be of enormous benefit. Shorter regimens were of great interest, so NIH and CDC funded several of these studies in Asian and African countries, insisting in most cases that the trials utilize a placebo control rather than the ACTG 076 regimen as a comparator.

Comment on the ethics of including a placebo arm in this trial.

Comment on the ethics of a U.S. agency providing funding to a foreign government to conduct trials that would not have been permitted in the U.S.