

Briefing Paper

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Preliminary results of Thai vaccine trial

- The results of a large clinical trial of an investigational HIV vaccine regimen, known as “RV144”, were released on 25 September and have been widely reported in the media.
- The results of the “test of concept” study, which involved 16,402 participants, indicate that the trialled vaccine is safe and modestly effective in reducing the risk of acquiring HIV. This is the first human study to show a significant reduction in the risk of acquiring HIV in a vaccine candidate trial.
- Results released so far are basic: the full report on the research will be released in October at the AIDS Vaccine Conference in Paris.
- The AIDS Vaccine Advocacy Coalition (AVAC) has called for widespread consideration of the trial and its implications, noting that it will take time and resources to analyse, understand and validate the data. However, AVAC described the findings as “astonishing” and a “landmark”, praising the trial collaborators, and volunteer participants for making the “historic study” possible.

The study:

- The study involved 16,402 Thai volunteers, male and female, age 18 to 30 (recruited from more than 60,000 interested people, of whom 26,675 people were screened). The trial was conducted in Chon Buri and Rayong Provinces in Thailand. It was a randomized, double-blind study. It was the largest human trial of an HIV vaccine ever conducted.
- The trial involved the “prime-boost” testing of two vaccines - *ALVAC HIV* (the prime) and *AIDSWAX B/E* (the boost), both containing synthetic fragments of subtype E, one of the most common strains of HIV circulating in Thailand and South-East Asia. The test vaccines used are manufactured by *sanofi pasteur*.
- The trial was “test of concept” study, designed to identify initial signs of promise in a product.
- All volunteers were HIV negative prior to entry. They were counseled throughout the trial, at each visit, to reduce risk behaviour. Study enrolment commenced October 2003 and was completed in December 2005. Vaccination (six immunisations of each person over six-months, with two different vaccine combinations), was completed July 2006. After vaccination was completed, volunteers were tested for HIV every 6 months for 3 years. Those who tested positive were given free access to care and treatment, including HAART, and were offered extended follow-up in a separate study (RV152).
- The study vaccines could not cause HIV infection (as they do not contain the entire virus, alive or killed).
- The trial collaborators acknowledged before the trial that any effect shown in the trial would be in respect of sub-type E only, and that follow-up studies would be necessary to establish whether a vaccine found to effective for the strains found in one geographical area would be effective for strains circulating elsewhere in the world.
- The trial looked at the vaccine regimen’s ability to reduce risk of HIV infection, and its ability to reduce viral load in people who became infected after enrolling in the trial. The percentage of people acquiring HIV while taking part in the study and taking the vaccine was compared to the percentage of study recipients in the placebo control group who acquired HIV.
- The study was sponsored by the U.S. Army Surgeon General and conducted by the Thailand Ministry of Public Health with support from the U.S. Army Medical Research and Materiel Command, and the National Institute of Allergy and Infectious Diseases (NIAID) (part of the National Institute of Health). It

was coordinated by the U.S. Military HIV Research Program. The collaborators were: the Royal Thai Army; the Vaccine Trial Center, Faculty of Tropical Medicine, Mahidol University; the Faculty of Tropical Medicine, Mahidol University; Chol Buri and Rayong Provincial Chief Medical Offices, Ministry of Public Health, Thailand.

- The trial team and Thai collaborators determined before the trial that a vaccine efficacy of 50% or higher would result in Thai licensure of the vaccine.

The findings:

- The study found that rate of HIV infection was roughly 30% lower among volunteers who were given the vaccine, compared to the control group who were given a placebo (74 placebo recipients acquired HIV, compared to 51 in the vaccine regimen arm).
- There was no evidence that the vaccine had any effect on the viral load of participants.
- The study results are considered to be statistically significant (in the context of its status as a “test of concept” study).
- The finding of a 30% risk reduction was presented as a “modest” effect.
- Given that the research was a “test of concept” study, and given the “modest effect” found, the trial results are being presented by the collaborators and commentators with cautious optimism. It is stressed that the trial results suggest that development of a vaccine is “possible” with further research. However, it is likely that these findings will re-energise HIV vaccine research.

References

- AIDS Vaccine Advocacy Coalition: Thai AIDS Vaccine Trial Update, available at www.avac.org
- U.S. Military HIV Research Program, RV 144 FAQs, available at www.hivresearch.org