

## Call for review of controversial AIDS vaccine trial

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A coalition of AIDS activist groups in the United States is calling for an independent review of the results of the AIDSVAX vaccine trial, amid claims that VaxGen Inc, the company running the trial, may have overstated the vaccine's [effectiveness](#) [1](Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the standard procedure, Phase II clinical trials gauge efficacy, and Phase III trials confirm it. in some racial groups.

The coalition said that VaxGen should release the raw data from the trial to a panel convened by the National Institutes of Health (NIH) for examination, in order to end a growing war of words over the validity of the findings.

Dr Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases, supported the call. The results of the trial, released last month, showed that the vaccine was ineffective, reducing the infection rate among people receiving the vaccine by just 3.8 percent, a result that surpassed even the most pessimistic predictions. More controversially, however, VaxGen maintains that in a subgroup of African-American and Asian trial participants, the vaccine did work, reducing the rate of infection by between 30 and 84 percent.

But the announcement drew strong criticism due to the small number of non-white volunteers [enrolled](#) [2]The act of signing up participants into a study. Generally this process involves evaluating a participant with respect to the eligibility criteria of the study and going through the informed consent process. in the trial — just 498 of the 5009 volunteers who completed the trial were non-white, and the finding of a protective effect was based on very small numbers of infections. Among black volunteers, there were just 13 infections — four in the vaccine group and nine in the group receiving a [placebo](#) [3]A dummy medical treatment, designed to have no pharmacological effect, administered to the control group of a clinical trial.. There were even fewer infections in the Asian group, with the claimed effectiveness based on just four infections.

While VaxGen has insisted that data analyses show that its findings are statistically significant, several prominent researchers and activists have criticised the company for talking up the trial results. Dr John Moore of Cornell University went so far as to describe the effect in blacks and Asians as a “statistical fluke,” claiming that similar results might be found if the data were analysed by signs of the zodiac.

“I doubt there is much to be learned other than the fact the vaccine didn't work,” he told AIDSmap.com. “Everything else is spin control.”

Martin Delaney of San Francisco's Project Inform said that “it would do a great deal of harm to stir up hopes for selected groups over a vaccine that has proven so ineffective overall.”

In a follow-up announcement on 31 March, the company reasserted its conclusion that the vaccine was protective among blacks and Asians, although it has not established any clear cause for differences in effectiveness based on race and was unable to provide any additional evidence of its validity.

In a further disappointing finding, VaxGen also said that follow-up studies had failed to show that among people who did become infected after being given the vaccine, there was any reduction in viral replication which might confer a protective effect.

Meanwhile, a “growing number” of shareholder lawsuits have been lodged against the company, alleging that VaxGen sought to cushion the drop in its market value when the trial results were released, according to the San Francisco Chronicle. The company denies the claims.

- [clinical trials](#)
- [preventative vaccines](#)

**Links:**

[1] <http://www.napwa.org.au/glossary/term/486>

[2] <http://www.napwa.org.au/glossary/term/489>

[3] <http://www.napwa.org.au/glossary/term/106>