The 505 vaccine is also designed to produce a different immune response in the body. The 505 vaccine produces T-cell and antibody responses against HIV envelope proteins, which were not present in the Step vaccine.

**Participant safety is foremost**

The first concern in every human study is the safety of the research participants. In previous studies, 390 people have received the same vaccine regimen being tested in HVTN 505, and this regimen has proven to be well-tolerated with no serious side effects attributed to it. The Ad5 vaccine has been given to nearly 1000 people without any serious adverse side effects reported. And, in response to what researchers learned from the Step Study, we have addressed safety issues in some key ways.

- The study group for HVTN 505 is made up of only Ad5 neutralizing antibody negative, circumcised men, a group that had no increased risk of HIV infection in the Step study.
- Working with an independent safety monitoring board, a real-time monitoring plan is in place. Each HIV infection is evaluated as soon as it is diagnosed to assess for no increased risk of infection in the vaccine group.

**The HVTN 505 vaccine regimen warrants further study**

The 505-like regimen was able to lower viral load and improve survival in vaccinated monkeys. We don’t know whether this result will be applicable to humans, and we don’t know what immune responses are needed in humans to control viral load. HVTN 505 is expected to provide insights into the types and specific focus of immune responses needed for viral load control.

The information gained from this study will help move the field forward and will inform the development of improved HIV vaccine designs.

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The HIV Vaccine Trials Network (HVTN) is an academically based research organization of scientists, educators and community members committed to eliminating the spread of HIV in the world by finding a safe and effective vaccine. The Network is supported through a cooperative agreement with the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). To learn more about the HVTN, please visit www.hvtn.org.

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**References:**