HIV VACCINE AWARENESS DAY

MAY 18 2023

Phase 1 mRNA HIV Vaccine Trials

In January 2022, the International AIDS Vaccine Initiative (IAVI) announced the launch of the first Phase I trial using mRNA-based technology to test a new HIV vaccine candidate. Two months later, the US National Institutes of Health (NIH) announced the launch of a second trial using mRNA technology. This technology has been successful in development of COVID-19 vaccines but has not been used to test HIV vaccine candidates until now.

Trials	IAVI G002	IAVI G003	HVTN 302
Name	A Phase 1 Study to Evaluate the Safety and Immunogenicity of eOD-GT8 60mer mRNA Vaccine (mRNA-1644) and Core-g28v2 60mer mRNA Vaccine (mRNA-1644v2-Core	A Phase I Trial to Evaluate the Safety and Immunogenicity of eOD-GT8 60mer delivered by an mRNA platform in HIV negative adults	A Clinical Trial to Evaluate the Safety and Immunogenicity of BG505 MD39.3, BG505 MD39.3 gp151, and BG505 MD39.3 gp151 CD4KO HIV Trimer mRNA Vaccines in Healthy, HIV-uninfected Adult Participants
Clinicaltrials.gov	NCT05001373		NCT05217641
Phase	1	1	1
Hypothesis	Sequential vaccination by a germline-targeting prime followed by directional boost immunogens can induce specific classes of B-cell responses and guide their early maturation toward broadly neutralizing antibody (bnAb) development through an mRNA platform	eOD-GT8 60mer delivered by an mRNA platform in HIV negative adults will induce immune responses in African populations as was seen in IAVI G001, which demonstrated this recombinant protein (eOD-GT8 60mer) safely induced immune responses in 97% of recipients, who were healthy U.S. adults	The BG505 MD39.3 soluble and membrane-bound trimer mRNA vaccines will be safe and well-tolerated among HIV-uninfected individuals and will elicit autologous neutralizing antibodies
Planned Dates	November 2021 – April 2023	May 2022 – 2023	February 2022 – October 2023
Sponsor	IAVI	IAVI	NIAID/NIH
Funder	Bill & Melinda Gates Foundation	PEPFAR via USAID and the Bill & Melinda Gates Foundation	NIAID/NIH
Participants	56 adults ages 18 to 50 years	18 healthy, HIV-negative adults	108 adults ages 18 to 55 years
Trial Sites	4 sites in the US (Atlanta; San Antonio, Seattle, Washington, DC)	2 sites: Kigali, Rwanda, and Tembisa, South Africa	11 sites in the US (Birmingham; Boston; Los Angeles; New York City; Philadelphia; Pittsburgh; Rochester; Seattle)
Vaccine Candidates	Two experimental HIV vaccines based on messenger RNA (mRNA) platform: 1. eOD-GT8 60mer mRNA Vaccine (mRNA-1644) 2. Core-g28v2 60mer mRNA Vaccine (mRNA-1644v2-Core)	One experimental HIV vaccine based on messenger RNA (mRNA) platform: 1. eOD-GT8 60mer delivered by an mRNA Vaccine platform (mRNA-1644)	Three experimental HIV vaccines based on messenger RNA (mRNA) platform: 1. BG505 MD39.3 mRNA 2. BG505 MD39.3 gp151 mRNA 3. BG505 MD39.3 gp151 CD4KO mRNA
Vaccine Manufacturer	Moderna	Moderna	Moderna
Immunogen Design	IAVI Neutralizing Antibody Center (NAC) at Scripps Research	IAVI Neutralizing Antibody Center (NAC) at Scripps Research	Scripps Consortium for HIV/AIDS Vaccine Development (CHAVD) and IAVI Neutralizing Antibody Center (NAC) at Scripps Research
Press Release	IAVI and Moderna launch trial of HIV vaccine antigens delivered through mRNA technology, January 27, 2022		NIH Launches Clinical Trial of Three mRNA HIV Vaccines, March 14, 2022

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mRNA technology is one of several "platforms" used in vaccine technology. mRNA platforms are designed to deliver a piece of genetic material that instructs the body to make a protein fragment of a target pathogen (such as HIV), which the immune system will hopefully recognize and mount a defense against. The platform is only one element in the complex process that is vaccine development.

Below is a snapshot comparing the new Phase 1 trials. While they use the same mRNA technology, they are testing different antigens, viral proteins that are targeted by the immune system. mRNA technology may be an important step forward to speed identification of the right target antigens for a protective response, but it alone does not address other challenges associated with HIV vaccine development, such as what antigen will be right.

ADDITIONAL RESOURCES

- ***The future of mRNA-based HIV vaccines is about more than speed***, https://www.iavi.org/iavi-report/the-future-of-mrna-based-hiv-vaccines-is-about-more-than-speed
- ***mRNA vaccines: facts, figures and the future***, https://www.scidev.net/global/features/mrna-vaccines-facts-figures-and-the-future/
- ***Cautious optimism for trials of mRNA-based HIV vaccine***, https://www.scidev.net/global/features/cautious-optimism-for-trials-of-mrna-based-hiv-vaccine/
- ***How HIV research paved the way for the Covid mRNA vaccines***, https://www.cnbc.com/video/2021/12/01/mrna-technology-game-changer-hiv-vaccine.html

SNAPSHOT: Phase 1 HIV Vaccine Trials Using the mRNA Platform

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Press Release	IAVI and Moderna launch trial of HIV vaccine antigens delivered through mRNA technology, January 27, 2022	IAVI and Moderna launch first-in-Africa clinical trial of mRNA HIV vaccine development program, May 18, 2022	NIH Launches Clinical Trial of Three mRNA HIV Vaccines, March 14, 2022