

US enrolls volunteers in large test of possible Zika vaccine

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In this Feb. 11, 2016 file photo, Dallas County Mosquito Lab microbiologist Spencer Lockwood sorts mosquitos collected in a trap in Hutchins, Texas, that had been set up in Dallas County near the location of a confirmed Zika virus infection. U.S. health officials have begun enrolling volunteers for critical next-stage testing of an experimental vaccine to protect against Zika, the mosquito-borne virus that can cause devastating birth defects in pregnant women. (AP Photo/LM Otero, File)

U.S. health officials have begun enrolling volunteers for critical next-

stage testing of an experimental vaccine to protect against Zika, the mosquito-borne virus that can cause devastating birth defects in pregnant women.

The first volunteer was vaccinated Wednesday at Baylor College of Medicine in Houston, as the National Institutes of Health gears up for a two-part study that aims to enroll at least 2,400 people in Texas, Florida, Puerto Rico and five at-risk countries: Brazil, Mexico, Panama, Costa Rica and Peru.

Zika has caused an epidemic of birth defects—including babies with abnormally small heads and brains—in parts of Latin America and the Caribbean, and continues to spread to a creeping list of other countries. For the U.S. the risk has largely been to travelers, although mosquitoes spread the virus in parts of southern Florida and Texas last year, where [health officials](#) remain on guard.

But while Zika largely disappeared from the headlines over the winter, mosquito season is fast approaching—and the risk persists internationally.

"It is imperative that public health research continue to work to contain the spread of the virus," Dr. Anthony Fauci, director of NIH's National Institute of Allergy and Infectious Diseases, said Friday in announcing the \$100 million study.

First-stage safety testing of a so-called DNA [vaccine](#) against Zika signaled no side effect concerns, Fauci said—allowing the NIH-created shots to progress to the next stage of testing that will help tell if they really work.

It's a two-part study. First, researchers will evaluate 90 healthy adults given different doses to determine the best one. Those volunteers will be

tested at Baylor, the University of Miami and University of Puerto Rico.

Once the correct dose is picked, the larger part of the study could begin as early as June at those sites and additional ones in the at-risk countries—giving 2,400 volunteers either the [experimental vaccine](#) or dummy shots. Pregnant women can't receive the experimental shots but women of child-bearing age can enroll. All the volunteers will be tracked for nearly two years to see if the vaccine really protects against Zika infection.

This is a totally new kind of vaccine. Traditionally, vaccines are made using a dead or weakened virus to train the body's immune system to recognize and fight that infection.

In contrast, the DNA vaccine works through trickery: It's made with a circular piece of DNA carrying genes from the Zika virus that, once in the body, make particles that resemble Zika enough to alert the immune system but cannot cause infection.

The NIH also is testing the safety of some more traditional Zika vaccine candidates, but the easier-to-make DNA vaccine was the first ready to advance to this second stage of human testing.

Don't expect a vaccine to be widely available any time soon. If Zika causes lots of illness this year, Fauci said researchers may have clues by early 2018 about how well the shots work—but if natural infections slow, they'll need many more volunteers to get an answer.

For most people, Zika causes no symptoms or only mild ones such as fever, aches, an itchy rash or red eyes. But aside from the pregnancy risk, Zika sometimes causes a temporary paralyzing condition called Guillain-Barre syndrome, and there's some evidence that it also may trigger heart problems in adults who previously were healthy.

And Zika is likely to become endemic in parts of the Americas, Fauci said. "I'm totally intent on getting this vaccine to the point it can be a usable vaccine."

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