# Dengue vaccine enters phase 3 trial in Brazil

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A female *Aedes aegypti* mosquito ingesting a blood meal. Credit: CDC

A large-scale clinical trial to evaluate whether a candidate vaccine can prevent the mosquito-borne illness dengue fever has been launched in Brazil. The vaccine, TV003, was developed by scientists in the laboratory of Stephen Whitehead, Ph.D., at NIH's National Institute of Allergy and Infectious Diseases (NIAID). The Butantan Institute, a non-

profit producer of immunobiologic products for Brazil, licensed the NIAID dengue vaccine technology and is sponsoring the placebo-controlled, multi-center Phase 3 trial using test vaccine produced in Sao Paulo.

Dengue fever is common in many parts of the tropics and subtropics and about half the world's population is at risk of infection. The World Health Organization estimates that up to 400 million dengue infections occur annually, resulting in 500,000 hospitalizations. More than 1.5 million cases of dengue were reported in Brazil in 2015.

Dengue is caused by any of four related viruses, termed serotypes DEN-1, DEN-2, DEN-3 and DEN-4, which are transmitted to people by Aedes aegypti mosquitoes. A person exposed to one dengue virus type gains immunity to that type, but not to the other three. In fact, a second infection with a virus type that differs from the first can lead to a more severe course of disease.

"Researchers in NIAID's Laboratory of Infectious Diseases spent many years developing and testing dengue vaccine candidates designed to elicit antibodies against all four dengue virus serotypes," said NIAID Director Anthony S. Fauci, M.D. "Earlier clinical trials of this candidate conducted in the United States by NIAID showed that it could elicit a robust antibody and cellular immune response after just one dose," he added. "Because the impact of dengue fever in Brazil is especially large and the country has an excellent health infrastructure, it is an ideal location to test the vaccine candidate."

The new trial aims to enroll almost 17,000 healthy people aged 2 to 59 years in 13 cities, beginning in Sao Paulo. Two-thirds of the volunteers will receive a single dose of the candidate vaccine, while one-third will receive an inactive placebo injection. Neither participants nor study staff will know which of the two groups a volunteer is in. All volunteers will

be monitored for five years through a combination of in-person visits to the health clinic and telephone or text communications from the investigators. The goal of the trial is determine if the candidate vaccine prevents dengue fever and to provide additional information about its safety. Although the trial is scheduled to last five years, the investigators hope to have early indications of the potential efficacy of the vaccine in less than two years. The principal investigator is Alexander Precioso, M.D., Ph.D., of the Butantan Institute.

**More information:** Additional information about the trial is available at ClinicalTrials.gov using the identifier NCT02406729.

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