

Research into preventive shot for Lyme disease continues to move forward

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Host-seeking blacklegged tick. Credit: Centers for Disease Control and Prevention (CDC), CC0

A Phase I clinical trial of a preventive Lyme disease shot developed by MassBiologics of UMass Chan Medical School is nearing completion and the next trial phase may begin as soon as next spring, according to

Mark Klempner, MD, professor of medicine and former executive vice chancellor for MassBiologics.

The [pre-exposure prophylaxis](#) being tested delivers a monoclonal antibody to provide immediate immunity against Lyme disease.

"We identified the single antibody that led to immunity and tested it in animals where it proved 100 percent effective," Dr. Klempner said.

Klempner explained that Lyme PrEP is not a vaccine. It prevents infection by delivering a single, human anti-Lyme antibody, or [blood protein](#), directly to a person rather than triggering their own immune system to make many antibodies as vaccines do. If a person's blood contains the correct antibody against the [bacteria](#), the antibody can kill *Borrelia* in the tick's gut before the bacteria has a chance to travel to the person.

"Our medicine is a transmission-blocking medicine, and it actually treats the tick and blocks the tick from depositing those bacteria in you by actually killing or immobilizing the bacteria in the gut of the tick," said Klempner.

During the Phase I trial, 48 volunteers who had never been exposed to Lyme disease are participating in the trial in Nebraska where the disease is not endemic. The goal of the trial is to make sure there are no major adverse reactions in humans and to see how long the Lyme PrEP antibody remains in the circulation to protect against Lyme disease. No major adverse reactions have been observed and injection site discomfort has been similar between Lyme PrEP and placebo recipients, Klempner said. The Lyme PrEP antibody lasts in circulation for at least nine months following the injection. The Phase I trial will end in August.

The Phase II-III clinical trial is under development and is anticipated to

begin as early as next spring, Klempner said.

"In order to demonstrate efficacy of Lyme PrEP to prevent Lyme disease, we will recruit participants with a heightened risk for Lyme disease, such as landscapers and people who spend lots of time outdoors, from populated areas where there is high risk of exposure to ticks that carry the Lyme disease bacteria. We will compare how the shot works in participants who get the shot to participants who do not," Klempner said.

Klempner expects that the shot could be licensed and available to the public in 2024.

Provided by University of Massachusetts Medical School

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