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Promising malaria vaccine to be tested in first large field trial

The vaccine can confer up to 100% protection and will be tested in 2,100 people on the west African island of Bioko.

Declan Butler

The island of Bioko, part of Equitorial Guinea, will be the site of a major malaria-vaccine trial. Robert Harding/Getty

A malaria vaccine that can provide up to 100% protection against the disease will be tested in a large clinical trial for the first time, to study its efficacy under real-world conditions.

The trial will begin in early 2020 on Bioko, an island off the coast of Equatorial Guinea, and will involve 2,100 people aged 2–50 years. The trial is intended to provide the efficacy and safety data needed for regulatory approval, says malaria researcher Steve Hoffman, who is leading the study and is chief executive of Sanaria, the company in Rockville, Maryland, that developed the vaccine. Equatorial Guinea's government and private energy companies are sponsoring the trial.

In laboratory studies, the vaccine, called PfSPZ, has proven the most effective malaria vaccine developed so far, giving healthy volunteers complete protection.

PfSPZ works by eliciting an immune response against the malaria parasite *Plasmodium falciparum*. It is made of sporozoites (SPZ), the stage in the malaria parasite's life cycle that infected mosquitoes inject into people during a bite. Sanaria isolates and purifies billions of sporozoites from farmed mosquitoes.

The vaccine is unique in using whole parasites as its ingredient; most candidate malaria vaccines include only a small number of genetically engineered parasite proteins. The abundance of proteins in the whole parasite vaccine explains why it provokes such a strong immune response.

But to be effective, PfSPZ must be injected intravenously. That poses challenges for mass vaccination campaigns because it is a more complex procedure than those typically used for other vaccines, where jabs penetrate the skin or muscles, or oral vaccines. However, Hoffman thinks the difficulties are surmountable.

Field efficacy

The trial on Bioko island, which has a population of about 280,000 people, is the first large test of the vaccine's effectiveness in a region where malaria occurs.

PfSPZ's efficacy in the field will inevitably be lower than in lab studies because people who have already had malaria are likely to have a weaker immune response, says Stefan Kappe, an immunologist who studies malaria at the Seattle Children's Hospital in Washington. Local strains of the malaria parasite will also differ from the one used in the vaccine, he adds.

But even a reasonably effective vaccine could have a big impact, says Kappe. The prevalence of malaria on Bioko has dropped from 45% to 12.5% in 15 years through the use of conventional measures such as indoor insecticide spraying and bed nets laced with the chemicals. But

experience in other parts of the world suggest that getting to zero is the most difficult part, he says. That might be possible only with the help of a vaccine. “This trial will be answering several questions for the first time, including whether a vaccine can completely eliminate malaria from this island environment,” he says.

If the trial is successful, Sanaria intends to carry out another one involving around 10,000 people on the island, says Hoffman. This study would compare disease levels between communities that receive the vaccine in addition to using standard malaria-prevention measures with levels in control communities that use only the standard measures, he says.

Hoffman expects the efficacy of the vaccine will be higher in this subsequent, larger trial than it will be in the upcoming trial, because of ‘herd immunity’ — when a sufficiently high percentage of a population is protected against a disease, making it difficult for the disease to spread to the few susceptible people left.

If the large trial is successful, Sanaria and its partners then plan to roll out the vaccine in the island’s entire population and assess its effectiveness.

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