

Danish malaria vaccine passes test in humans

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For many years, a team of researchers at the University of Copenhagen have been developing a vaccine that can protect against pregnancy malaria, from which 220,000 people die every year.

Now, they have come a significant step closer to marketing such a



vaccine. In a phase I clinical trial reported in *Clinical Infectious Diseases*, the vaccine was found safe to use, passing the test by inducing the right antibody response in the blood.

"It is a great milestone for us to be able to show that our vaccine is completely safe and induces the exact antibody response in the blood we want—it is the immune response that has been shown to be connected with protection from pregnancy malaria. The next step is to document that it prevents pregnancy malaria in African women who would otherwise have contracted the disease," says the main author, Associate Professor Morten Agertoug Nielsen, from the Department of Immunology and Microbiology.

Safety First

The researchers conducted a standard randomised, double-blind study. This means that the <u>test subjects</u> were randomly given the vaccine and placebo, respectively, and neither the subjects nor the researchers performing the study knew which subjects received the vaccine.

The effect of the vaccine was examined among 36 German male and female volunteers. The researchers were able to detect the right immune response with antibodies against the malaria parasite in the blood, and the subjects showed no serious side effects.

The German test subjects are described as "malaria naïve," because they are not and will not be exposed to the malaria parasite, and therefore will never develop pregnancy malaria. They were nevertheless used as test subjects to document that the vaccine is safe and appears to work before it is introduced in a group of African women vulnerable and at risk of developing pregnancy malaria.

"Of course, we will be doing more tests, because we want to take the



vaccine as far as we can. We are therefore cooperating with hospitals in Benin in Africa, where we can conduct studies in women at risk of developing the disease. We expect to be able to publish the results of these studies sometime next year," says co-author of the study, Professor Ali Salanti from the Department of Immunology and Microbiology.

Cooperation Ensures Medicine for People in Need

The researchers' journey towards a malaria vaccine began with Ali Salanti's discovery of the placental protein hook to which the malaria parasite may attach itself. Subsequently, Ali Salanti and his research team have been applying this knowledge to produce an actual vaccine against the fatal disease.

"Our development and production of the vaccine has only been possible due to our close public-private collaborations. It is a strong example of how such a constellation can make it possible to develop medicine for people in need, including people with few resources," says Professor Ali Salanti.

In academia, it is also unusual to see researchers take their discovery further to <u>clinical trials</u>. Clinical trials can be extensive and expensive, and therefore the pharmaceutical industry is typically the one developing and safety-testing drugs before introducing them in the market. But in this case the researchers have managed to do so themselves.

"The next step in the process is a phase two clinical trial, which will show whether the vaccine is still safe, but also whether it can prevent disease. Concurrently, we have developed a method for transforming the vaccine into a virus-like particle. This increases the antibody response. But the crux of the matter is whether it is sufficient for attacking all the different forms of the protein hook found in the malaria parasite," says Associate Professor Morten Agertoug Nielsen.



More information: Benjamin Mordmüller et al, First-in-human, randomized, double-blind clinical trial of differentially adjuvanted PAMVAC, a vaccine candidate to prevent pregnancy-associated malaria, *Clinical Infectious Diseases* (2019). DOI: 10.1093/cid/ciy1140

Provided by University of Copenhagen

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