

# KEMRI | Wellcome Trust

## **R21 Phase III trial results.**

After the successful completion and positive results from the Phase I (Kenya) and II (Burkina Faso) R21 vaccine trials, who include those at the KEMRI Wellcome Trust Research Programme, have now published the results of the trial ahead of peer review. See [link](#).

The Phase III trial enrolled 4800 children aged 5 months to 3 years of age in four countries across Africa. This included Mali, Burkina Faso, Tanzania, and Kilifi in Kenya.

The Phase III trial evaluated the ability of the vaccine to prevent clinical malaria in the 12-month period after primary series vaccinations in Kenya. It also assessed the safety of the vaccine and its ability to illicit a good immune response. The vaccine was efficacious across all 5 sites. Efficacy as measured by time to the first malaria episode was 75% in seasonal sites and 68% in standard sites. The vaccine in the seasonal sites was administered ahead of the malaria season, while at the standard sites where transmission occurs throughout the year the vaccine had no specific time of administration.

Malaria is and remains one of the leading causes of death in children, with the majority of cases experienced in Africa. In its 2022 report the WHO noted that though there has been a decline of deaths due to malaria to just over 600,000 in 2020, Africa still accounts for over 95% of the global burden and 96% of Malaria deaths.

There has been concerted efforts by researchers to improve the current tools in the fight against malaria which includes malaria prophylaxis, insecticide treated nets and most recently the RTS, S malaria vaccine. To build on the long-standing work on malaria at the KWTRP, the team in Kilifi led by Prof. Mainga Hamaluba has been on course to carry out trials for the R21 Vaccine, including conducting the Phase I trial which first looked at the safety of the R21 vaccine in Africa.

In the Phase III trial, the 600 children recruited for the trial in Kilifi, children were randomised to one of two groups: one group receiving the R21 vaccine and the other a licensed rabies vaccine. The screened eligible children were given the first 3 doses of the vaccine at 28-day intervals (primary series) while the fourth dose (booster) was given 12 months after the third dose.

The antibody and efficacy responses a month after the primary series was higher in the younger vaccinees (5-17 months compared to 18-36months). The vaccine targets the CSP antigen like the RTS'S vaccine but can be used at a much lower dose than the RTS'S vaccine, uses a simpler saponin adjuvant, and can be manufactured at very large-scale and at a lower cost per dose. Making it highly cost effective.

The vaccine was also evaluated for safety with the researchers looking out for both adverse events of special interest (AESI's) and serious adverse events (SAE. The vaccine was seen to be safe with no significant safety concerns. Although there was a trend to more febrile convulsions in R21 vaccinees this wasn't significant.

The team plans to further evaluate the vaccine to study the optimal schedule for booster doses, and assess how long immunity lasts in early childhood.

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## Note to the Editor

The **Kenya Medical Research Institute (KEMRI)-Wellcome Trust Research Programme** is a partnership between KEMRI, Oxford University and the Wellcome Trust. We conduct basic, epidemiological, and clinical research in parallel, with results feeding directly into local and international health policy and aims to expand the country's capacity to conduct multidisciplinary research that is strong, sustainable and internationally competitive. [www.kemri-wellcome.org](http://www.kemri-wellcome.org)

The **Nuffield Department of Medicine, Centre for Tropical Medicine and Global Health** at the University of Oxford is a collection of research groups permanently based in Oxford, in Africa (Kenya, Uganda and DRC) and in Asia (Thailand, Vietnam, Laos, Myanmar, Cambodia, Indonesia and Nepal). Aiming to tackle infectious diseases, from malaria, TB and HIV to neglected tropical diseases and emerging infections, our research ranges from clinical studies to behavioural sciences, with capacity building integral to all of our activities.