

RTS,S vaccine is safe and efficacious against clinical malaria in young children living in Korogwe District

Participating Institutions

National Institute for Medical Research, Tanga centre Tanga, Tanzania
London School of Hygiene and Tropical Medicine (LSHTM), UK,
Centre for Medical Parasitology (CMP), University of Copenhagen, Denmark
PATH Malaria Vaccine Initiative, US
GlaxoSmithKline, Belgium



Introduction

Malaria is a public health problem especially in communities living in lowlands. Although the malaria affects all age groups, children below the age of five years are known to be more susceptible to the disease. There are several malaria control strategies which we all know. To achieve effective control of the disease, search for malaria vaccine is necessary to complement other existing malaria control tools such as insecticide treated bed nets, indoor residual spray and early treatment using efficacious antimalarial drugs. RTS,S is a new and more advanced vaccine in research compared to other malaria vaccine undergoing clinical trial. RTS,S induce immune response against *Plasmodium falciparum* once the parasites invade human host. RTS,S is designed to trigger the immune system to defend against the *Plasmodium falciparum* malaria parasite as soon as it enters the human host's bloodstream and/or when the parasite infects liver cells. This prevents the parasite from maturing and multiplying in the liver and from reentering the bloodstream, where the host would begin to show symptoms of infection. To stimulate an immune response to the malaria parasite, RTS,S fuses a critical circumsporozoite (CS) protein, the surface protein that helps the parasite invade human liver cells, with a protein found in GSK Bio's hepatitis B vaccine. The addition of GSK's proprietary Adjuvant System strengthens the immune response even further.

Procedure

This clinical trial was conducted in Korogwe, Tanzania, and Kilifi, Kenya, in the year 2007 and 2008, enrolled 894 children of 5-17 months. The delivery of the vaccine was done within the Expanded Program on Immunization (EPI) clinics. Korogwe site enrolled 447 from 18 villages from the three dispensaries, namely Ngombezi, Makuyuni and Mbaghai. The trial was led by Dr. Lorenz von Seidlein and Dr. John Lusingu from NIMR Tanga. The trial was designed to test the safety and efficacy of RTS,S malaria vaccine using GSK's proprietary vaccine adjuvant known as AS01. Children who participated in this randomized clinical trial received either three doses of the RTS,S/AS01 vaccine or a human rabies vaccine

Results

With this sample, the candidate RTS,S/AS01E was shown to reduce clinical malaria episodes by 53% for up to an average of eight months for the two sites (Korogwe and Kilifi). Dr. Lusingu says the results provide evidence that RTS,S/AS01E malaria vaccine was able to prevent to a larger extent the clinical cases of malaria in young children who are the main victims of the disease. Dr. Martha Lemnge from NIMR Tanga says: "This is an exciting moment in the history of malaria research and control because an effective malaria vaccine will add on to other effective tools like the insecticide-treated mosquito bed-net and antimalarials" Commenting on the results, the Director General of NIMR Dr. Andrew Kitua said his institute is "particularly pleased with the progress made so far and look forward to working with other partners to eventually eliminate malaria." Findings from this work was published online on the 11th December 2008 in the *New England Journal of Medicine*, USA. Presentation of these findings in Tanzania focusing the health sector officials and other stakeholders was done in Dar es Salaam in January 2009.

Conclusion

A large phase three clinical trial is planned to commence in 2009 and will recruit over 16,000 children in 11 sites from 7 African countries Tanzania included. "We are committed and well prepared to participate in this large phase three multi-centre trial involving many sites." concluded Dr. Lusingu.

Acknowledgement

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