

AMANET launches a Phase 2 Clinical Trial of Candidate Malaria Vaccine GMZ2

The African Malaria Network Trust (AMANET), through a grant received from the European and Developing Countries Clinical Trials Partnership (EDCTP), has launched a multi-site phase IIb clinical trial of the candidate malaria vaccine GMZ2 to assess its efficacy and safety among young children with a high risk of getting malaria in Burkina Faso, Gabon, Ghana and Uganda. Composed of *Plasmodium falciparum* glutamate rich protein (GLURP) and merozoite surface protein 3 (MSP3), GMZ2 induces an immune response that impedes multiplication of the parasite stages that lead to clinical symptoms, complications or even death. *P. falciparum* is the most common malaria parasite in Africa and is responsible for almost all of the estimated one million fatal malaria cases per year.

A total of 1870 children aged between 1 and 5 years from four participating sites; Banfora - Burkina Faso, Iganga – Uganda, Lambaréné - Gabon, and Navrongo - Ghana will be taking part in what will be the largest trial to date for malaria candidate vaccine, GMZ2. The first site to be initiated for this trial is the Medical Research Unit (MRU) of the Albert Schweitzer Hospital (ASH) in Gabon, where 460 children will be followed up for two years starting in 2010. Other sites involved in this trial are expected to initiate vaccinations and follow up between December 2010 and March 2011.

“Gabon is the first country in Africa to run the early phase trial of the GMZ2 vaccine among malaria endemic populations. The vaccine was tested in adults and subsequently in a small group of children and found to be safe. We feel very proud to again lead Africa in advanced stage trials for this vaccine which might eventually provide us with an efficacious tool to fight malaria, a disease that continues to claim hundreds of lives of children here in Gabon and across the continent” says Dr Saadou Issifou, the principal investigator from Gabon on this trial. Other principal investigators participating in this phase IIb trial include Dr Sodiomon Sirima from Centre National de Recherche et de Formation sur le Paludisme (CNRFP) - Burkina Faso; Dr Kalifa Bojang from Medical Research Centre (MRC) Laboratory (UK) - The Gambia, Prof. Fred Kironde from Makerere University - Uganda and Dr Frank Atuguba from Navrongo Health Research Centre - Ghana.

In this multi-site trial, half the number of the participating children will receive 3 doses each of 100 micrograms of GMZ2, the test vaccine while the other half (comparator group) will receive rabies vaccine. In three months, each child will have received three doses of either the test vaccine or comparator. All children will be observed for a period of 2 years. During this time, safety, immune response and clinical information will be collected and assessed to answer the question of whether this candidate malaria vaccine protects against malaria.

“It is a great pleasure for SSI and me, that the GMZ2 vaccine will be tested in a phase II trial initially in Gabon and soon also in other African countries. I am very impressed with the organization and professionalism of the team in Gabon and hope that the results will lead to a phase III trial and finally a vaccine that can safely and effectively be administered to small children” says Michael Theisen. GMZ2 was invented by Dr Michael Theisen of the Staten Serum Institut, Copenhagen (SSI) where further development of the product has been taking place.

The GMZ2 vaccine to be used in this trial is manufactured by Henogen S.A, a Belgian bio-engineering company.

GMZ2 works by targeting the malaria parasite in the blood stage (merozoite) of the infection and in doing so stimulates the body's immune system to produce agents (antibodies) that target GLURP and MSP3 receptors on the malaria parasite. These killer agents (GLURP and anti-MSP3 antibodies) have been demonstrated to be able to completely inhibit malaria parasite growth in animal experiments. Earlier studies of the GMZ2 candidate malaria vaccine were done by the University of Tübingen among malaria naïve German adults with support from the European Malaria Vaccine Initiative (EMVI) now known as European Vaccine Initiative (EVI). Recent studies done in Africa were conducted by the Medical Research Unit of the Albert Schweitzer in Gabon with funding from the European Commission – AIDCO and EDCTP. All these studies confirmed that GMZ2 is safe for use among humans. It has been further confirmed that GMZ2 is able to induce the production of specific antibodies and memory B-cells targeting the plasmodial proteins GLURP and MSP3 at high levels.

Trials of this candidate vaccine are being conducted under the auspices of the GMZ2 Consortium, which is funded by EDCTP and operates under several work packages fostering research capacity strengthening, networking and the management of this vaccine candidate. AMANET is the Consortium coordinator and sponsor for these trials. Other partners for this consortium are, the Centre National de Recherche et de Formation sur le Paludisme (CNRFP) in Burkina Faso, Statens Serum Institut (SSI) in Denmark, the Medical Research Unit at Albert Schweitzer Hospital (MRU-ASH) in Gabon, the Medical Research Council (MRC) Laboratories in The Gambia, University of Tübingen, Germany, Makerere University in Uganda and the London School of Hygiene and Tropical Medicine (LSHTM) in the UK.

This trial is registered with PACTR [ATMR2010060002033537], a public registration system for Malaria, TB and HIV/AIDS research in Africa.

For further information on GMZ2 Consortium activities, kindly contact AMANET through the following;
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