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Immunogenicity of Merozoite Surface Protein-1 based malaria vaccine candidate antigen in combination with two novel adjuvants, MF59 and Montanide ISA 51

The *Plasmodium cynomolgi-toque* monkey *(Macaca sinica)* system which is highly analogous to the *P. vivax*-human system was used in this pre-clinical trial to test the immunogenicity and safety of baculovirus-expressed, His-tagged 19kDa C-terminal region of *P. cynomolgi* major merozoite surface protein-1 (MSP 1p 19) with two experimental adjuvants, MF59 and Montanide ISA51. This trial comprised four groups of animals. Groups 1 and 3, comprising three animals each, were immunized with MSP 1p 19+MF59 (Chiron) and Montanide ISA51 (SEPPIC) respectively in three doses. Groups 2 and 4, comprising two animals each, served as the respective adjuvant controls. No adverse reactions were observed as a result of immunization. After each immunization, anti- MSP 1p19 antibody responses were assayed by ELISA. Three weeks after the third immunization, the ELISA titers in group 1 had reached 3.7x103 and group 3 showed a higher titer of 5.3x105. Peripheral blood mononuclear cells were assessed for in vitro proliferative responses against the MSP 1p19 antigen. Although animals of all groups showed similar non-specific cellular proliferative responses observed in the two immunized groups. The levels of cytokines in these PBMC supernatants showed induction of specific cytokines following immunization. These results indicate that the two novel adjuvant tested are safe and, antigenic formulation with Montanide ISA51 was immunogenic. It is interesting to note that immunization of toque monkeys with MSP1p19+Montanide ISA51 resulted in a higher humoral immune response, similar to the responses earlier observed in combination with Freunds adjuvant. Whether, this vaccine-induced immunity is protective against a malaria infection remains to be evaluated.