2021
May 11
Webinar

41st Global Summit and Expo on
Vaccines & Immunology

# Stability study of a recombinant protein-based on Plasmodium vivax Circumsporozoite Protein (CSP) candidate for a malaria vaccine

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Recently, our research group demonstrated that a formulation containing the yPvCSP-AllCT chimeric protein, based on CSP from Plasmodium vivax (PvCSP), and the adjuvant Poly (I:C) (Invivogen) induced high long-term antibody titers as well as a protective effect in immunized mice, indicating a great potential to future clinical trials[1]. Based on these results, it has become necessary to evaluate the stability of the vaccine formulation, as this type of study is essential during the developmental stages of a product[2]. Thus, our objective is the expression and purification of the yPvCSP-AllCT protein, and the evaluation of the stability of the formulation at three different storage temperatures and in two different pharmaceutical forms, liquid and lyophilized.

The recombinant protein was expressed from Pichia pastoris yeast and was purified by FPLC. Its stability was evaluated over 180 days, and tests such SDS-PAGE, Western Blot, and CD were performed. For evaluation of immunogenicity, C57BL/6 mice were immunized with 10 µg of protein in 50 µg/dose of Poly (I:C) adjuvant. IgG antibodies were measured by ELISA.

The recombinant protein, in a liquid formulation, proved to be stable only when stored at -20°C for 180 days. When in a lyophilized formulation, the protein remained intact during 6 months when stored at -20°C and 5°C, and for 120 days in 25ºC.

The presented results demonstrate that the vaccine formulation remained stable in some of the tested conditions. Considering the difficulty in maintaining the cold chain in the locals where malaria is an endemic disease, our data is promising. This project was financed by FAPESP (São Paulo Research Foundation)