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Nanoclinical evaluation of toxicity and safety of the use of the H5N8 Avian Influenza vaccine

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Highly pathogenic avian influenza (HPAI) A(H5) virus can be transmitted from infected birds to various mammals, including humans (Alexander & Brown, 2009). Avian influenza viruses (AIVs) belong to the Orthomyxoviridae family (Rafique et al., 2023) and are RNA viruses with segmented genomes that are highly unstable upon reassortment, facilitating new genetic traits that may affect their transmissibility, pathogenicity, and even antigenicity (Shi & Gao, 2021). Although there are no reported cases of human-to-human transmission, there is an alarming scenario that the virus may adapt resulting in a new pandemic (Lin et al., 2024). Our proposal was to establish a nonclinical safety and toxicity study in a rodent model of the H5 influenza vaccine and adjuvant, to support future safety tests in humans. Male e female Wistar rats 90 days after the last administration of two doses of the H5 influenza vaccine + adjuvant did not demonstrate systemic comorbidities or serious alterations in the central nervous system. The cellularity of blood elements remained within normal values for the species. Total and absolute leukocytes were within normal parameters despite the occurrence of differences in the total numbers of eosinophils, neutrophils and monocytes, with values lower than 1% of the total number of leukocytes. Biochemical changes in urea levels and hepatic transaminasetype enzymes were observed. These changes did not accompany the histopathological changes described in this study. In conclusion, the H5 Influenza Vaccine + adjuvant administered was well tolerated locally and clinically, without compromising the functioning of vital organs. All findings found in the study are in accordance with what is expected for an adjuvanted vaccine and the immunological response, such as the presence of inflammatory cells and the increase in the proliferative response of lymphoid tissue. This study was financed by Butantan Foundation and the São Paulo Research Foundation (FAPESP), Brasil. Process Number 2021/11946-9, 2024/06260-9.

Biography

Master's degree in Immunology from the University of São Paulo, PhD in Immunology from the University of São Paulo and a PhD/Sandwich from the University of Paris VII Denis Diderot. Scientific Researcher VI at the Laboratory of Development and Innovation Center. He has experience in the areas of Immunology, Cell Biology and Pharmacology, with an emphasis on Tumor Immunology. Currently, He works with animal models for the non-clinical studies of toxicity and safety of repeat dose vaccine, evaluation of reproductive toxicity and immunobiological at the Butantan Institute.

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