VAC_14 - Safety and Immunogenicity of the Anticocaine Vaccine UFMG-VAC-V4N2 in Wistar rat

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Introduction: In recent years, the most promising treatment for cocaine addiction is an immunological strategy called an anti-cocaine vaccine. A new molecule UFMG-V4N2, has been shown to be able to produce anti-cocaine antibodies in murine models, these antibodies reduce the passage of the drug to the brain. Developing a formulation with components approved for use in humans requires toxicity tests at repeat doses.

Objectives: This research is a pre-clinical, interventional, longitudinal study to assess the local and systemic toxicity and immunogenicity of the UFMG-V4N2 in rat model.

Methodology: Forty adult animals, male (20) and female (20) of the specie Wistar were divided into two groups: Control has received adjuvant and treated group received 0,3mL of the vaccine UFMG-V4N2 through 4 intramuscular injections on days 0, 7, 21, 28, and 42. Food consumption and water intake were recorded daily, and the animal's weight was monitored. Tissue samples were immediately collected after the euthanasia for histopathologic analysis. Biochemical and hematological tests and ELISA were used to evaluate vaccine safety and immune response induction parameters.

Results: In the first inoculation, no deaths occurred in any groups and none of the animals had lesions at the inoculation site. No significant differences were observed in the means of body weight, weekly food and water intake. Both groups showed increased creatinine values, accompanied by statistically significant differences in urea values. No noteworthy changes were found in the systemic histopathological assessment. Evaluation of the injection site showed moderate focal panniculitis and myositis with mild fibrosis. Evaluation of the lymph nodes revealed mild lymphoid hyperplasia and evaluation of the spleen showed moderate lymphoid hyperplasia in all vaccinated animals. The mean levels of anti-cocaine IgG (OD) were significantly higher in the vaccinated rats when compared to the baseline.

Conclusion: The anti-cocaine vaccine UFMG-V4N2 presented a favorable safety profile and induced immune response in a rat model. The results are in accordance with criteria required by the regulatory agencies to proceed with the vaccine for future clinical trials.

Keywords: Anti-cocaine vaccine, Pre-clinical study, Toxicology