VAC_03 - Safety and reactogenicity of COVID-19 (Recombinant) vaccine doses administered in 4-, 8- or 12- weeks interval between the first two doses

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Introduction: COVID-19 is the disease caused by the SARS-CoV-2 coronavirus and is featured as clinical wide spectrum. The infection can vary among asymptomatic to severe cases and causing death. In 03/11/20, the pandemic status was declared. Until 01/28/24, WHO points to 774.496.936 cases of COVID-19 and 7.026.465 deaths in the world. One of the best medical approaches for halting the spread of infectious diseases is vaccination. The COVID-19 vaccines could do it as there was a significant morbi/mortality COVID-19 reduction and the pandemia is over (ASEFA *et al.*, 2023) (WHO, 2024). Although covid-19 (Recombinant) vaccine was widely administered in the beginning of vaccination campaign in Brazil, there have been some concern about its reactogenicity.

Objectives: Follow up the safety and reactogenicity of three covid-19 (Recombinant) vaccine doses administered in 4-, 8- or 12-weeks interval between the first two doses.

Methodology: Phase IV clinical trial, opened, randomized (ClinicalTrials.gov: NCT05157178). These data have not published yet. For the intention-to-treat analysis, the protocol considered all vaccinated participants with security data in one post-vaccination follow up at least.

Results: 1,258 participants were enrolled. By monitoring reactogenicity information, the most commonly solicitated Adverse Event (AE) within seven days of vaccine administration for the three doses were pain and sensibility at the injection site and headache for all groups. Besides, myalgia, somnolence, malaise, fatigue and joint pain completed the list of the most common reported AE for all doses. Considering all the solicitated AE, pain at the site injection had the longest median time of duration 3.2 days. Add, more than 80% of the participants have not shown any non-solicitated AE. In general, they were mild and moderate and nearly 3% needed medical assistance. Among them, just three participants were hospitalized, not classified as causal related to vaccine. Also, any VITT case happened.

Conclusion: So, the safety and reactogenicity monitoring from 3 doses points to most of AE was not severe, being solved in few days after covid-19 (Recombinant) vaccine administered in 4-, 8- or 12- weeks interval between the first two doses.

Keywords: Covid-19 (Recombinant) vaccine; Safety and reactogenicity