

# Immunogenicity and safety of the BBIBP-CorV vaccine in patients with autoimmune inflammatory rheumatic diseases and immunosuppressive therapy in a monocentric cohort

Batool Zamani<sup>1</sup>, Amin Moradi Hasan-Abad<sup>1</sup>, Ahmad Piroozmand<sup>1</sup>, Mahsa Dehghani<sup>1</sup>, Maryam Arfaatabar<sup>2</sup>, and Hossein Motedayyen<sup>1</sup>

<sup>1</sup>Kashan University of Medical Sciences

<sup>2</sup>Islamic Azad University

January 30, 2024

## Abstract

**Introduction:** Vaccination plays a fundamental role in mastering the COVID-19 pandemic and protecting vulnerable groups. Persons with autoimmune inflammatory rheumatic diseases (AIIRD), on immunosuppressive therapies, are prioritized for vaccination. However, data concerning immunogenicity and safety of the BBIBP-CorV vaccine in immunosuppressed patients are not found. This study presents data on the efficacy and safety of the BBIBP-CorV vaccine in immunosuppressed patients compared to healthy controls. **Methods:** Study population consisted of 100 healthy controls and 100 patients with AIIRD. Vaccination was performed according to national guidelines with the BBIBP-CorV vaccine. SARS-CoV2 neutralizing antibody titers were quantified by ELISA before initial vaccination and 1–3 months after secondary vaccination. Adverse events were assessed before study initiation and 7 days after the second dose. Disease activity was studied before entering the study and 3–8 weeks after the second dose. **Results:** Vaccination-induced positive immunogenic response rates and SARS-CoV2 neutralizing antibody titers were significantly lower in the AIIRD patients than healthy subjects ( $P < 0.05$ ). There are significant differences in neutralizing antibody titers among patients suffering from RA, SLE, SSc, and AS ( $P < 0.01-0.05$ ). The rates of seropositive vaccine responses were similarly distributed across all diseases. Healthy and AIIRD individuals had a similar profile in adverse events. No significant difference was observed in SARSCoV2 antibody titers between subjects suffering from side effects and those who did not have. SARS-CoV2 neutralizing antibody levels were significantly higher in SARS-CoV2-infected persons than noninfected subjects ( $P < 0.01-0.05$ ). Seropositive subjects had a significant increase in the percentage of vaccine-related adverse events compared to seronegative persons ( $P < 0.05$ ). Despite a minor change in the disease activity of patients with RA and SLE, disease activity indices were overall stable in the AIIRD patients. **Conclusion:** The BBIBP-CorV vaccine is effective in the development of neutralizing antibody in immunosuppressed patients without considerable reactogenicity or induction of disease flares.

## Hosted file

Manuscript.docx available at <https://authorea.com/users/723242/articles/708010-immunogenicity-and-safety-of-the-bbibrp-cov-vaccine-in-patients-with-autoimmune-inflammatory-rheumatic-diseases-and-immunosuppressive-therapy-in-a-monocentric-cohort>

## Hosted file

Figures.docx available at <https://authorea.com/users/723242/articles/708010-immunogenicity-and-safety-of-the-bbibrp-cov-vaccine-in-patients-with-autoimmune-inflammatory-rheumatic-diseases-and-immunosuppressive-therapy-in-a-monocentric-cohort>