# Patients taking rituximab could benefit from third COVID-19 vaccine dose

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New research presented this week at ACR Convergence, the American College of Rheumatology's annual meeting, shows immunocompromised patients using rituximab (a drug used to treat diseases like rheumatoid

arthritis) were able to produce antibodies against COVID-19 (seroconvert) after receiving a third COVID-19 vaccine dose, even if there was no development of the antibody after the first two doses of the vaccine.

COVID-19 is caused by the novel SARS-CoV-2 coronavirus. This disease has led to the deaths of millions worldwide, including those who are immunocompromised. Following the Centers for Disease Control and Prevention's (CDC) recommendation that certain immunocompromised patients receive a third dose of a COVID-19 vaccine, the American College of Rheumatology released updated vaccine guidance for patients with rheumatic diseases, including patients using rituximab therapy. Researchers set to find out how efficient and safe a third vaccine dose would be for these patients.

"Patients using B cell depleting therapies such as rituximab show severe COVID-19 disease courses. Our previous studies could show a reduced humoral and cellular immune response after two vaccinations with an mRNA vaccine in rituximab-treated patients," said Michael Bonelli, MD, Associate Professor of Medicine in the Division of Rheumatology at the Medical University of Vienna, Austria and the study's co-author. "However, it was unclear whether patients would benefit from an additional booster vaccination and if the same or a different vaccination regime would be more efficient and safer."

To address the efficacy and safety of a third COVID-19 vaccine dose, researchers conducted a blind, randomized clinical trial comparing the additional third dose vaccination in individuals who received the initial regimen of an mRNA vaccine (Pfizer–BioNTech or Moderna) but did not mount a significant antibody response. The study sought to determine the difference in SARS-CoV-2 antibody development between using the third dose of the same vaccine versus switching to the other vector based vaccine (Oxford-AstraZeneca).

Sixty patients undergoing rituximab treatment, who did not form antibodies after their primary mRNA vaccination with either the Pfizer-BioNTech or Moderna vaccines, were assigned to receive a third dose of either the same mRNA or the vector vaccine by Oxford-AstraZeneca. The primary endpoint was the difference in the SARS-CoV-2 antibody development rate between vector and mRNA vaccinated patients by week four. Key secondary endpoints included the overall antibody development and cellular immune response. Safety was also assessed throughout the study.

The primary endpoint result showed that by week four, antibody development rates were comparable between the patients who were given the vector vaccine (6/27 patients, 22%) and mRNA (9/28 patients, 32%) vaccines. Secondary endpoints showed that overall seroconversion (development of antibodies against COVID-19) was 27%, of which T-cell responses were observed in 100% (20/20) of vector vaccine patients versus 81% (13/16) of mRNA vaccinepatients. Additional secondary endpoints results showed newly induced cellular immune responses in 82% (9/11) patients. There were no reported serious adverse events related to immunization.

"The results from our study support efficacy and safety of an additional booster vaccination in immunosuppressed patients, whether it's the same vaccine or a different one," says Dr. Bonelli. "Cellular and humoral immune responses can be induced in B-cell depleted patients undergoing rituximab treatment. Our data provides evidence that non-seroconverted immunosuppressed patients should receive an additional booster vaccination."

The study's authors go on to state that ongoing clinical trials are needed to investigate the effect of an additional vaccination in B-cell depleted patients who did not develop a sufficient antibody response after a third vaccination or only developed low levels anti-SARS-CoV-2 antibodies.

Researchers believe whether a cellular and or humoral antibody development response can be maintained over time also needs to be addressed.

**More information:** Michael Bonelli et al, Additional Heterologous versus Homologous Booster Vaccination in Immunosuppressed Patients Without SARS-CoV-2 Antibody Seroconversion After Primary mRNA Vaccination: A Randomized Controlled Trial [abstract]. *Arthritis Rheumatology* (2021). Available at acrabstracts.org/abstract/addi … ed-controlled-trial/

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