

Methotrexate drug holiday improves flu vaccine efficacy in rheumatoid arthritis patients

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People with RA who stop taking methotrexate treatment for just two weeks after they have a seasonal flu shot can improve the vaccine's efficacy without increasing RA disease activity, according to new research findings presented this week at the 2017 ACR/ARHP Annual Meeting in San Diego.

Rheumatoid arthritis (RA) is a chronic disease that causes pain, stiffness, swelling, and limitation in the motion and function of multiple joints. Though joints are the principal body parts affected by RA, inflammation can develop in other organs as well. An estimated 1.3 million Americans have RA, and the disease typically affects women twice as often as men.

Methotrexate, a widely used immunosuppressant, can lower [vaccine efficacy](#) in people with RA. So researchers in Seoul, Republic of Korea, set out to investigate whether patients with RA could improve their [response](#) to influenza vaccinations by temporarily pausing methotrexate use for two weeks after their [flu shot](#).

"RA patients are more susceptible to infections, including seasonal flu, due to their underlying abnormal immune function and the treatment-associated immune suppression," said Jin Kyun Park, MD, Assistant Professor of Medicine at Seoul National University Hospital, and a lead author of the study. "RA patients taking methotrexate are at even higher risk of infection and infection-related complications, so it's important

that they be vaccinated against preventable infectious diseases. However, the immune suppression decreases [vaccine response](#). To overcome this shortcoming, our group has been working on a novel immunization protocol for RA patients to optimize vaccine response, including increasing immunogenicity of flu vaccines."

In this prospective, multicenter, randomized, parallel-group trial conducted from October 2016 to January 2017, 316 RA patients who were taking a stable methotrexate dose were randomly assigned to two groups: 156 continued their regular methotrexate and 160 discontinued their dose for two weeks after receiving their flu shot. All participants were vaccinated with a seasonal, quadrivalent influenza vaccine containing H1N1, H3N2, B-Yamagata and B-Victoria.

The study's primary outcome measurement was the frequency of a satisfactory response to the vaccine, which was defined as the patients having a fourfold or greater increase in hemagglutination inhibition (HI) antibody titer at four weeks after vaccination against two or more vaccine strains. They also measured seroprotection rate and fold-change in antibody titers relative to baseline in geometric mean titer.

The researchers found that 75.5 percent of the patients who temporarily discontinued their methotrexate dose achieved a satisfactory vaccine response compared to 54.5 percent of patients who continued their regular dosing. After vaccination, the seroprotection rate was higher for all four antigens measured in the group who held off methotrexate for two weeks than those who continued. The RA patients who paused their methotrexate dose after vaccination also achieved a higher increase of H1 antibody titer in geometric mean titer for each antigen. All patients in the study tolerated the vaccine well. Disease activity after vaccination was the same in both patient groups.

"The findings of this study have several potential clinical implications.

First, we show a novel, effective, but simple way to improve vaccine response in RA patients who take methotrexate. Holding methotrexate for two weeks after vaccination improved vaccine response significantly without increasing disease activity. Therefore, [patients](#) should be advised to hold methotrexate for two weeks after vaccination," said Dr. Park.

"This approach can be applied to other vaccines, such as pneumonia or zoster. Also, despite the well-known clinical experience that joint symptoms improve three to six weeks after starting methotrexate, our findings indicate that the drug has immediate effects on immune response. Short-term methotrexate discontinuation could be considered in situations of immunologic challenges such as infections or surgery."

This study only assessed the effect of a temporary methotrexate discontinuation on the vaccine's immunogenicity, meaning antibody production, after flu shot, said Dr. Park.

"Since antibody production does not always guarantee immune protection, further studies are needed to address as to whether the increased immunogenicity by holding [methotrexate](#) for two weeks can prevent flu infection," he added.

Provided by American College of Rheumatology

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