



## Synopsis

# Temporary 2-week suspension of methotrexate treatment to enhance COVID-19 vaccine response in people with immune-mediated inflammatory diseases: the VROOM RCT

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## Plain language summary

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## Plain language summary

### What was the question?

Methotrexate is used in the treatment of inflammatory conditions such as rheumatoid arthritis and psoriasis. These conditions occur due to the body's immune system – the part of the body that protects us from infection – getting out of control and attacking itself. Methotrexate can reduce these attacks and help control these inflammatory conditions, but methotrexate also dampens the body's response to vaccinations including against COVID-19. People who take methotrexate do not get as much protection from vaccination against COVID-19. We wanted to see if pausing methotrexate for 2 weeks immediately after a COVID-19 booster vaccine could improve the protection against COVID-19.

### What did we do?

We recruited 383 people taking methotrexate for different inflammatory conditions and randomly allocated half of them to continue their methotrexate and half to pause their methotrexate for 2 weeks after their booster. We measured levels of antibodies created by the vaccine in the blood that can fight the virus in both groups of people.

### What did we find?

Four weeks after vaccination, people who paused methotrexate had about twice as many COVID-19 antibodies in their blood. This improved vaccine response was also present 12 and 26 weeks later. Blood from those who paused methotrexate was also better at killing the virus. The benefit was similar at different ages, in different diseases, with different vaccine types, in people who had a previous COVID-19 infection and those who had not. In the first month, people who paused methotrexate had more disease flare-ups, but these did not last long and were mostly self-managed. Quality of life was similar in both groups.

### What does this mean?

Temporarily stopping methotrexate for 2 weeks after the COVID-19 booster vaccine allowed a better immune response to the vaccine.

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