Research shows mRNA vaccination is safe and effective, even with chronic inflammatory diseases

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Chronic inflammatory diseases, such as rheumatic diseases, psoriasis or chronic inflammatory bowel diseases are autoimmune diseases in which the immune system targets the body. This leads to misdirected inflammations in the body which flare up repeatedly. Many of these diseases are therefore kept under control with immunosuppressive therapy, i.e. a form of treatment that suppresses the immune response.

People undergoing immunosuppressive therapy were excluded from the clinical trials for approval of the new mRNA vaccines against COVID-19. There has therefore been no data available to date on how the vaccination works in this particular group, what the side effects are, and whether they can possibly lead to new flares of inflammation.

A Kiel research team from the Cluster of Excellence "Precision Medicine in Chronic Inflammation" (PMI) has investigated this and published their results now in the scientific journal *Annals of the Rheumatic Diseases*. The researchers show for the first time worldwide that the new mRNA vaccines against COVID-19 are effective and well tolerated for people with chronic inflammatory diseases and undergoing immunosuppressive therapy.

"There was a great deal of concern among many patients with chronic inflammatory diseases who are undergoing corresponding immunosuppressive therapy that the vaccination either does not work sufficiently because of the suppressed immune system, or could lead to new flares of inflammation," explained coordinating author Bimba Hoyer, professor of rheumatology at Kiel University (CAU) and head of the Comprehensive Center for Inflammation Medicine at the University Medical Center Schleswig-Holstein (UKSH), Campus Kiel. "We know from influenza vaccinations that they are effective in people undergoing immunosuppressive therapy and are well tolerated. However, for many other vaccines, there is little to no data on efficacy and safety for this particular group of patients. In addition, the new mRNA vaccines utilize a completely new mode of action that has not been used before, so there was an urgent need for research here," added Hoyer.

The research team examined 25 patients with various chronic inflammatory diseases at different times after vaccination with an mRNA COVID-19 vaccine, and compared the reactions to those of healthy vaccinated patients. All patients were receiving immunosuppressive therapy and had low disease activity or none at all at the time of vaccination. The vaccination itself was not part of the study, as all participants were in priority group 1 and were therefore already vaccinated at the start of the governmental vaccination campaign in Germany.

"Vaccination with one of the mRNA vaccines did not lead to any disease activity in the patients in our

study, and we could not detect any flares of inflammation by either clinical or molecular methods," said Dr. Ulf Geisen, first author of the study and scientist at the Department of Internal Medicine I, Rheumatology, UKSH, Campus Kiel. In addition, neither different nor more frequent side effects were observed in the group with chronic inflammatory diseases than in the control group or in the clinical trials for approval. In fact, no person in this group developed a fever, whereas this symptom occurred in some of the healthy participants.

All people undergoing immunosuppressive therapy also showed a sufficient vaccine response to the vaccines, based on the current state of knowledge. However, in a few patients the levels of antibodies measured, which serve as markers of successful vaccination, were lower than in the control group. "This may possibly be due to the higher age of these patients. Even in healthy elderly people, the antibody levels are usually lower after vaccination," explained Hoyer. "The lower antibody levels could have an impact on how long the vaccination remains effective. We want to examine this in future studies. It is possible that the group of people undergoing immunosuppressive therapy may need a booster dose of the vaccine earlier than healthy people," said Hoyer.

The group investigated consisted predominantly of patients with rheumatoid arthritis, but vaccinated people suffering from other rheumatic diseases, the chronic skin disease psoriasis or from chronic inflammatory bowel diseases such as Crohn's disease were also investigated. "Some of these diseases differ significantly in their symptoms, because they affect very different areas of the body, like the joints, skin or intestines. At the same time, the underlying disease mechanisms are surprisingly similar, as we have demonstrated in numerous studies. Therefore, the drug groups used also overlap in these different diseases," explained co-author and cluster spokesperson Professor Stefan Schreiber, who is also director of the Department of Internal Medicine I at the UKSH, Campus Kiel, and director of the Institute of Clinical Molecular Biology (IKMB) at the CAU and UKSH. "That is why we investigated patients with various diseases in this study, but subgroups receiving the same immunosuppressive therapy. So far, we have not seen any differences in the efficacy or tolerability of vaccinations between the various diseases and treatments studied," added Schreiber.

More information: Ulf M Geisen et al. Immunogenicity and safety of anti-SARS-CoV-2 mRNA vaccines in patients with chronic inflammatory conditions and immunosuppressive therapy in a monocentric cohort, *Annals of the Rheumatic Diseases* (2021). DOI: 10.1136/annrheumdis-2021-220272

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