

# mRNA-based COVID-19 vaccines are safe for high-risk patients, shows study

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Spare a thought for patients with impaired immunity during the COVID-19 pandemic. Their condition puts them at high risk of severe complications from COVID-19, but also creates uncertainty about the

safety and effectiveness of the available vaccines that could protect them.

A new study in *Frontiers in Oncology* helps to put this catch-22 situation to rest by finding that two popular mRNA-based vaccines are well tolerated by such high-risk patients. The trial found that the vaccines were safe and did not cause unexpected adverse events in a group of patients with various cancers, neurological, and rheumatological conditions that are associated with immunosuppression. The results will reassure vaccine-hesitant patients that the vaccines are safe, even for the immunocompromised.

By now, many of us have received a COVID-19 vaccine, including those based on new mRNA technology, and this has allowed society to largely reopen in many countries. Vaccine-mediated protection, along with the rise of the milder Omicron variant, means that the number of COVID-19 patients with [severe disease](#) has dropped significantly over the past year. However, it hasn't been plain sailing for everyone.

The original clinical trials for these vaccines were conducted in healthy volunteers. While this is [standard practice](#), it means that high-risk immunocompromised patients, such as those taking immunosuppressant drugs for neurological conditions, were not included in the trials.

## **Previous catch-22 for immunocompromised patients**

This lack of trial data could lead such patients to be understandably hesitant about the safety and effectiveness of the vaccines. However, in a cruel irony, they are also at high risk of severe COVID-19 complications, suggesting that they would greatly benefit from vaccine-mediated protection. In an effort to cast more light on the safety of mRNA-based COVID-19 vaccines, a group of researchers in Italy conducted a study to assess COVID-19 vaccine safety in high-risk

patients.

The researchers enrolled 566 high-risk patients in the trial, and administered two doses of either the Pfizer-BioNTech or Moderna mRNA vaccine as normal. The patients reported any adverse events in a questionnaire, and the questions focused on the first week after each dose.

The most common reported side-effects at the injection site included pain, swelling, and a rash, whereas the most common general side-effects included tiredness, headache, chills and muscle pain. Such side-effects are also commonly reported by people with a fully functioning immune system who have received the vaccine. The study also found no evidence that the underlying disease of the patients was affected, and vaccination did not interfere with the patient's ability to undergo standard treatment for their conditions.

## **No higher incidence of adverse events in high-risk patients**

"Strikingly, we found that the occurrence of adverse events in these high-risk patients is comparable to that reported in vaccine trials conducted in the general population," explained Prof Nicola Silvestris of the University of Bari Aldo Moro, Italy, the senior author.

"Our patients did not show a higher incidence of severe adverse events and we did not see an increased risk of discontinuation of treatment programs due to vaccination. Therefore, vaccination for COVID-19 is confirmed as safe, even in this group of high-risk patients."

The results will help to calm fears among [immunocompromised patients](#) who are at high risk of severe COVID-19 complications, but are also

worried about the [side-effects](#) of the vaccine.

"Our main recommendation based on the results of this study is that vaccination for COVID-19 is strongly recommended and the safety profile is reassuring," said Dr. Maria Teresa Lupo-Stanghellini of the San Raffaele Scientific Institute, Italy, lead author on the study.

"Our ongoing [safety](#) monitoring of the COVID-19 [vaccine](#) continues in the spirit of offering the best prevention and care for our [patients](#)."

**More information:** mRNA-COVID19 vaccination can be considered safe and tolerable for frail patients, *Frontiers in Oncology*, 2022. [DOI: 10.3389/fonc.2022.855723](#) , [www.frontiersin.org/articles/1...onc.2022.855723/full](#)

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