

Vaccines and Lupus: What to Know Amid COVID-19

Vaccines Protect Against Disease

What are vaccines?

Vaccines help protect against serious infections like the flu or pneumonia by imitating an infection and safely developing immunity to the pathogen (bacteria or virus that causes disease) targeted by the vaccine. Vaccines for specific diseases cause the immune system to produce cells that will learn and remember how to fight that disease when you are exposed to it in the future. Some vaccines need only a single dose for protection, while others require an initial injection followed by a booster.ⁱ

Why are vaccines important?

Vaccines are among the best public health measures ever developed. They have greatly reduced the numbers of adults, children and infants who develop and could die from serious infectious diseases. Vaccines are important to protect the person who gets the vaccine and helps prevent spreading diseases to others.ⁱⁱ

Will I get sick from a vaccine?

The vaccine imitates a very mild version of an infection, but rarely causes illness. Sometimes you might get minor symptoms such as a fever but this is a sign that the body is building up immunity to the disease.ⁱⁱⁱ

Do vaccines cause side effects?

Like any medication, vaccines can cause side effects, but serious side effects are very rare. For most people, side effects are mild such as soreness at the spot where a shot was given.^{iv}

How long does it take for the vaccine to work?

Usually it takes two to three weeks for the body to produce enough cells that protect against infection. That's why it is possible that a person can be infected just before or soon after being vaccinated because the vaccine has not had enough time to provide protection.^v

Are vaccines safe?

Vaccines are tested carefully in clinical trials before the US Food and Drug Administration (FDA) will approve them for use. The FDA also inspects the manufacturing plants where the vaccine will be produced to make sure strict guidelines are followed. Even after a vaccine is approved, the FDA and the US Centers for Disease Control and Prevention (CDC) monitor the vaccines' use to detect any long-term safety concerns.^{vi}

Why are vaccines recommended for people with lupus?

The CDC recommends specific vaccines to protect people who are at greatest risk for illness, including people with chronic conditions and weakened immune systems. Lupus lowers the immune system's ability to fight infections.^{vii}

What vaccines can people with lupus take?

The CDC recommends talking with your doctor about vaccines, particularly because lupus lowers the immune system's ability to fight off infections like the flu. Many are safe, but people with lupus should not take vaccines that contain live viruses.

The following vaccines are recommended by the CDC for people with lupus:

- The injectable flu shot
- Pneumonia vaccine
- Human papillomavirus (HPV) vaccine
- Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccine

There are other vaccines that appear safe for lupus patients and may be recommended by your physician. The following vaccines are made with live viruses, so according to the CDC, may not be safe for people with lupus:

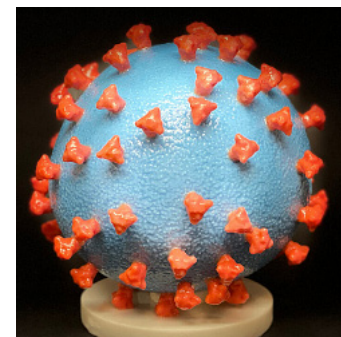
- Nasal spray vaccine for the flu
- Varicella (chickenpox) vaccine
- Herpes Zoster (Shingles) vaccine*
- Measles, Mumps, Rubella (MMR) vaccine^{viii}

* In 2017 the FDA approved a recombinant (not live) herpes zoster vaccine called Shingrix. However, it has not been approved yet for use in immunocompromised patients, including lupus patients. Studies are currently underway which will inform future recommendations for this group.

Vaccines Against COVID-19

Why is it important for people with lupus to be protected from COVID-19?

Many people with lupus and other rheumatologic diseases take medications that suppress the immune system, increasing their risk for infections like COVID-19. According to the American College of Rheumatology (ACR) COVID-19 Vaccine Clinical Guidance, preventing COVID-19 is a priority for these people.^{ix}



Can the COVID-19 vaccine trigger flares of autoimmune disease?

The ACR COVID-19 Vaccine Clinical Guidance notes that there is little data to support this possibility.^x

What vaccines are being used to protect against the novel coronavirus?

Currently, many clinical trials are testing COVID-19 vaccines in thousands of people. Two of the three approved by the US Food and Drug Administration for Emergency Use Authorization as of February 27, 2021 use the same new technology – the messenger RNA vaccines from Pfizer and Moderna. The recent adenovirus-vector vaccine that was granted Emergency Use Authorization is from Johnson & Johnson/Janssen and uses a different technology.

- Messenger RNA (mRNA) vaccines contain synthetic genetic material modeled after the genetic material found in SARS-CoV-2 (the virus that causes COVID-19). Our cells use the genetic material to manufacture small pieces of the “spike” protein that cover the surface of the virus and allow it to attach to and enter human cells. The mRNA vaccine causes various cells of the immune system to fight the virus in different ways. For instance, immune cells known as B cells produce molecules called antibodies that stop the spike protein from attaching to human cells. By blocking the attachment of the virus to human cells, the antibodies help prevent cells from getting infected with the virus and ultimately keep you from getting seriously ill. mRNA vaccines have been in development for years, but the Pfizer/BioNTech and Moderna vaccines are the first to complete all stages of drug development and receive approval in the US, albeit under Emergency Use Authorization.^{xi, xii} Four other companies are also making mRNA vaccines for COVID-19.

Two other technologies are being tested to provide additional vaccines against COVID-19.

- Adenovirus-vector vaccine uses a virus that doesn’t cause disease called adenovirus as a vector (or carrier) of genetic material for the spike protein from SARS-CoV-2. Once the adenovirus vector is inside our cells, the genetic material (in this case, DNA) provides the template for our cells to produce spike proteins. The spike proteins prompt B cells to make antibodies that fight the virus if we become infected in the future.^{xiii, xiv} In addition to the vaccine from Johnson & Johnson/Janssen, adenovirus-vector vaccines are being developed by Oxford-AstraZeneca and other companies.
- Protein subunit vaccines include fragments of the spike protein from SARS-CoV-2 to help our immune system recognize the spike protein as non-human. The vaccines are made with chemicals called adjuvants that boost their effectiveness. B cells then develop antibodies to the spike protein to help prevent SARS-CoV-2 from infecting our cells. This helps prevent severe illness from COVID-19. Protein subunit vaccines are being developed by Novavax, Sanofi/GSK, and other companies.^{xv}

Is the vaccine from Pfizer and BioNTech safe?

So far Pfizer and BioNTech have reported no serious safety concerns from their vaccine. The mRNA vaccine from Pfizer and BioNTech was reviewed by the FDA and by an independent committee of scientists and public health experts on December 10. The independent committee, by a strong majority vote, recommended for the FDA to grant Emergency Use Authorization. This recommendation is based on safety and efficacy clinical trial data. On December 11, the FDA issued an Emergency Use Authorization that allows the Pfizer/BioNTech vaccine to be distributed in the US. This is the first Emergency Use Authorization for a SARS-CoV-2 vaccine to prevent COVID-19 in individuals aged 16 years and older.^{xvi}

Is the vaccine from Moderna safe?

Moderna has not reported serious safety concerns from its vaccine to date. Their vaccine was reviewed by the FDA and by an independent committee of scientists and public health experts on December 17. The independent committee recommended for the FDA to grant Emergency Use Authorization. This recommendation is based on safety and efficacy clinical trial data.^{xvii} On December 18, the FDA issued an Emergency Use Authorization that allows the Moderna vaccine to be distributed in the US to prevent COVID-19 in individuals aged 18 years and older.^{xviii}

What is the difference between the Pfizer/BioNTech and Moderna vaccines?

The two vaccines are very similar. Both allow cells of the immune system known as B cells to produce molecules called antibodies that stop the spike protein from attaching to human cells. By blocking the attachment of the virus to human cells, the antibodies help prevent cells from getting infected with the virus.^{xi} The main difference is the age groups the two were tested in. The Pfizer/BioNTech vaccine was tested in individuals age 16 and over, while Moderna's vaccine was tested in adults age 18 and older.^{xx}

Is the vaccine from Johnson & Johnson/Janssen safe and effective?

The adenovirus vector vaccine from Johnson & Johnson/Janssen was reported safe and effective by data from the Phase 3 ENSEMBLE clinical trial with 43,783 participants. The vaccine was deemed safe and effective by the US Food and Drug Administration on February 24, 2021. An FDA advisory committee reviewed the data and recommended it be granted Emergency Use Authorization. Granted February 27, the authorization allows the Johnson & Johnson/Janssen vaccine to be distributed in the US to prevent COVID-19 in individuals 18 years of age and older.^{xxi}

How effective are these three vaccines?

Data from the clinical trials testing the Pfizer-BioNTech vaccine showed that it was 95% effective at preventing COVID-19 illness after 28 days in people who had never been infected as well as who had been infected with the illness.^{xxii} Data from the Moderna vaccine clinical trials showed 94.1% effectiveness against COVID-19 infection and 100% effectiveness against severe COVID-19.^{xxiii}

Among all participants from different geographies and including those infected with an emerging viral variant, Johnson & Johnson/Janssen's COVID-19 vaccine was 66% effective overall in preventing moderate to severe COVID-19, 28 days after vaccination. It also was shown 85% effective overall in preventing severe disease and 100% effective in preventing hospitalization and death 28 days after vaccination.^{xxiv}

Which vaccines for the novel coronavirus will people with lupus be able to take?

The Lupus Research Alliance (LRA) recently convened a meeting of physicians and scientists from academia, government, and pharmaceutical companies. Physicians who treat lupus patients, scientists who study vaccines in lupus patients, and two people with lupus also took part. The group discussed special considerations that must be taken for people who have weakened immune systems.

The LRA is developing a report on their recommendations and will provide it to the community as soon as possible. Based on previous knowledge of vaccines, the experts did not identify any reasons that the SARS-CoV-2 vaccines would not be appropriate for lupus patients. But they also emphasized the lack of data since the new vaccine technologies were not tested in lupus patients. Importantly, the group underscored the urgent need to generate clinical and research data on SARS-CoV-2 vaccine responses in lupus patients. Following up on these recommendations, the Lupus Research Alliance and its affiliate Lupus Therapeutics, engaged key investigators to design and conduct such a study.

Why is the LRA conducting a study of vaccines in people with lupus?

Because many of the COVID-19 vaccines in use and those under development utilize new technologies, assessing how the new vaccine platforms might impact people with lupus is very important and timely. Therefore, the LRA is investing \$3 million in a vaccine research project to evaluate the immune responses to different COVID-19 vaccines among people with lupus as they are approved by the US Food and Drug Administration for emergency authorization.

Further details are to be announced in the coming weeks. As always, your decision regarding vaccinations against SARS-CoV-2 and any other pathogens must be made with your doctor.

Are there guidelines for COVID-19 vaccination from the American College of Rheumatology?

The American College of Rheumatology issued COVID-19 Vaccine Clinical Guidance February 8, 2021 on the use of the Pfizer and Moderna vaccines which had been granted Emergency Use Authorization as of that date. The Guidance recommends that people who have autoimmune diseases and other inflammatory and musculoskeletal diseases be vaccinated because the benefit of protection against COVID-19 outweighs potential risk. It also recommends taking either the Pfizer or Moderna vaccine – the two vaccines that ACR’s panel have reviewed to date – and both based on mRNA technologies. Most importantly, they recommend working closely with your physician who can apply the Guidance recommendations to you, knowing your medical situation and history.^{xxv}

Is there a preference in the Guidance for Pfizer or Moderna vaccines for people with lupus and other autoimmune diseases?

No. According to the ACR COVID-19 Vaccine Clinical Guidance, patients should get whichever vaccine is available to them. Both use the same mRNA technology and are both two-dose vaccines.^{xxvi} The Guidance is a living document intended to evolve over time as new data is available.

Should people be vaccinated if they are having a flare?

Based on information on other vaccines, in general it would be better to be vaccinated when your disease is inactive. However, the ACR COVID-19 Vaccine Clinical Guidance recommends not delaying vaccination unless people are hospitalized.^{xxvii}

Should you hold off taking immunosuppressive drugs?

The ACR COVID-19 Vaccine Clinical Guidance provides your physician with specific recommendations for timing immunosuppressant drugs with your vaccination.^{xxviii}

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- i Understanding how vaccines work. Centers for Disease Control and Prevention.
 - ii Six things you need to know about vaccines. Centers for Disease Control and Prevention.
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 - iv Six things you need to know about vaccines. Centers for Disease Control and Prevention.
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 - xii Coronavirus disease (COVID-19): Vaccines. World Health Organization.
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 - xv Understanding How COVID-19 Vaccines Work. Centers for Disease Control and Prevention
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 - xvii Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine. CDC. Advisory Committee on Immunization Practices. Centers for Disease Control and Prevention
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 - xvii How CDC Is Making COVID-19 Vaccine Recommendations. Centers for Disease Control and Prevention
 - xviii Understanding mRNA COVID-19 Vaccines. Centers for Disease Control and Prevention
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